

Do not use if the blister seal is cut or broken.

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Whippany, NJ 07981  
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**ALL DAY STRONG®**  
**ALEVE®**  
naproxen sodium tablets, 220 mg (NSAID)  
Pain reliever/fever reducer

**STRENGTH TO LAST 12 HOURS** **10 TABLETS**

Drug Facts	Purposes	Drug Facts (continued)	Uses
<b>Active ingredient (in each tablet)</b> Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*	Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug	<ul style="list-style-type: none"> <li>are age 60 or older</li> <li>have had stomach ulcers or bleeding problems</li> <li>take a blood thinning (anticoagulant) or steroid drug</li> <li>take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</li> <li>have 3 or more alcoholic drinks every day while using this product</li> <li>take more or for a longer time than directed</li> </ul>	<ul style="list-style-type: none"> <li>temporarily relieves minor aches and pains due to:                             <ul style="list-style-type: none"> <li>muscular aches</li> <li>menstrual cramps</li> </ul> </li> <li>backache</li> <li>headache</li> <li>the common cold</li> <li>toothache</li> <li>temporarily reduces fever</li> </ul>

No Copy in Blister Area

Bayer 00000

Lot Number  
Exp Date  
Country Of Origin

0 00000 00000 0

<p><b>Drug Facts (continued)</b></p> <p><b>Warnings</b> Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:  <ul style="list-style-type: none"> <li>hives</li> <li>swelling (wheezing)</li> <li>skin redness</li> </ul>                     If an allergic reaction occurs, stop use and seek medical help right away.  <b>Stomach bleeding warning:</b> This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:  <ul style="list-style-type: none"> <li>are age 60 or older</li> <li>have had stomach ulcers or bleeding problems</li> <li>take a blood thinning (anticoagulant) or steroid drug</li> <li>take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</li> <li>have 3 or more alcoholic drinks every day while using this product</li> <li>take more or for a longer time than directed</li> </ul> <b>Heart attack and stroke warning:</b> NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.  <b>Do not use</b>  <ul style="list-style-type: none"> <li>if you have ever had an allergic reaction to any other pain reliever/fever reducer</li> <li>right before or after heart surgery</li> </ul> <b>Ask a doctor before use if</b>  <ul style="list-style-type: none"> <li>the stomach bleeding warning applies to you</li> <li>you have a history of stomach problems, such as heartburn</li> <li>you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke</li> <li>you are taking a diuretic</li> <li>you have problems or serious side effects from taking pain relievers or fever reducers</li> </ul> <b>Ask a doctor or pharmacist before use if you are</b>  <ul style="list-style-type: none"> <li>under a doctor's care for any serious condition</li> <li>taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin</li> <li>taking any other drugs</li> </ul> <b>When using this product</b>  <ul style="list-style-type: none"> <li>take with food or milk if stomach upset occurs</li> </ul> </p>	<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if</b>  <ul style="list-style-type: none"> <li>you experience any of the following signs of stomach bleeding:                              ● feel faint ● vomit blood                              ● have bloody or black stools                              ● have stomach pain that does not get better</li> <li>you have symptoms of heart problems or stroke:                              ● chest pain ● trouble breathing                              ● weakness in one part or side of body                              ● slurred speech ● leg swelling</li> <li>pain gets worse or lasts more than 3 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>you have difficulty swallowing</li> <li>it feels like the pill is stuck in your throat</li> <li>redness or swelling is present in the painful area</li> <li>any new symptoms appear</li> </ul> <b>If pregnant or breast-feeding,</b> ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.  <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.                 </p> <p><b>Directions</b>  <ul style="list-style-type: none"> <li>do not take more than directed</li> <li>the smallest effective dose should be used</li> </ul> <b>Adults and children 12 years and older</b>  <ul style="list-style-type: none"> <li>take 1 tablet every 8 to 12 hours while symptoms last</li> <li>for the first dose you may take 2 tablets within the first hour</li> <li>do not exceed 2 tablets in any 8- to 12-hour period</li> <li>do not exceed 3 tablets in a 24-hour period</li> </ul> <b>Children under 12 years</b>  <ul style="list-style-type: none"> <li>ask a doctor</li> </ul> </p> <p><b>Other information</b>  <ul style="list-style-type: none"> <li>each tablet contains: sodium 20 mg</li> <li>store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).</li> </ul> <b>Inactive ingredients:</b> FD&amp;C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide                 </p> <p><b>Questions? 1-800-395-0689</b></p>
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FDA00225-2

DRUG FACTS INFO	Updated 09/18/18	
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	8 pt.-bold italic*	8 pt.
Subheadings	>6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	>0.5 pt.	0-0.5 pt.
Headlines	>0.5 pt. min.	0.5 pt.
Box and Barlines†	>0.5 pt. min.	2.5 pt.
Characters Per Inch	No more than 28	<28

\* Headings are to be at least 20pt larger than Body Text.  
 \*\* Drug Facts Title to be larger than all other type size used in OTC IVDs. Recommendations 2:24a-1a.



**ALLEVE STRONG**  
**ALEVE**  
naproxen sodium tablets, 200 mg (NSAID)  
Pain relief. Fever reducer.

**10 TABLETS**  
**STRENGTH TO LAST 12 HOURS**

**Read Via Blister Card Before Use.**

**Uses:** Temporarily relieve minor aches and pains and temporarily reduce fever. **Warning:** Allergy or hypersensitivity reactions to naproxen sodium or other NSAIDs may include: hives, facial swelling, asthma (wheezing) or cough. Stomach pain or irritation may occur. **Caution:** Naproxen sodium may increase the risk of bleeding. **Do not take if you are taking aspirin, aspirin-like products, or other NSAIDs.** **Do not take if you are taking blood thinners or other blood thinning drugs.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.**

**Directions:** Take one tablet every 8 to 12 hours with food or a meal. **Do not take more than 2 tablets in 24 hours.** **Do not take more than 2 tablets in 24 hours.** **Do not take more than 2 tablets in 24 hours.**

**Warnings:** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.**

**Side Effects:** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.**

**Precautions:** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.**

**Interactions:** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.**

**Contraindications:** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.**

**How to Use:** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.**

**Storage:** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.**

**Other information:** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.**

**Keep out of reach of children.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.** **Do not take if you are taking other NSAIDs.**

**Lot/Exp Date Area**

Lot:   
Exp:   
Mylan Pharmaceuticals, LLC   
Mylan, PA, USA

DRUG FACTS INFO: (Modified Format – updated 5/1/16)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt.	-
Drug Facts Continued	7 pt.	-
Headings*	7 pt- <b>bold italic</b> *	4.5 pt.
Subheadings	≥6 pt.	4.5 pt.
Body Text	≥6 pt.	4.5 pt.
Bullets	5 pt.	6 pt.
Leading	≥0 pt.	4.5 pt.
Headlines	0.5 pt. rule	-
Box and Bulletins†	>0.5 pt. rule	-
Characters Per Inch:	No more than 39	>39

\* Headings are 20 pts or larger; 20 pts larger than Body Text.  
† Box design may be unboxed, and color contrast used to highlight Drug Facts info.

Actual Size 100%

FDA00222-1

DRUG FACTS FACTS	UNITED STATES	ACTUAL IN FILE
CATEGORY	Human	Human
Drug Facts Title	8.1 pt	8.1 pt
Drug Facts Content	8.1 pt	8.1 pt
Warnings	8.1 pt	8.1 pt
Directions	8.1 pt	8.1 pt
Other information	8.1 pt	8.1 pt
Inactive ingredients	8.1 pt	8.1 pt
Questions?	8.1 pt	8.1 pt

Bayer HealthCare Bayer HealthCare Bayer HealthCare

**Drug Facts**

**Active ingredient (in each tablet)** Purposes  
Naproxen sodium 220 mg (naproxen 200 mg)  
(NSAID)<sup>1</sup> Pain reliever/fever reducer  
(nonsteroidal anti-inflammatory drug)

**Uses** temporarily relieves minor aches and pains due to:  

- muscular aches
- muscle aches
- backache
- menstrual cramps
- headache
- toothache
- the common cold
- temporarily reduces fever

**Warnings** **Key alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:  

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin redness
- rash
- diarrhea

 If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains an NSAID, which may cause stomach bleeding. The chance is higher if you:  

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take 5 or more alcoholic drinks every day or others)
- take more or for a longer time while using this product
- take more or for a longer time than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer:  

- right before or after heart surgery

**Ask a doctor before use if:**  

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver or kidney disease, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

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**ALL DAY STRONG**  
**ALEVE**  
naproxen sodium tablets, 220 mg (NSAID)<sup>1</sup>  
Pain reliever/fever reducer

LOT: EXP: MADE IN: 100%

**STRENGTH TO LAST 12 HOURS 10 TABLETS**

Do not use if tear strip with "Bayer HealthCare" is torn or missing.  
 Tear strip to open completely.  
 Product information: www.aleve.com

Bayer

**Drug Facts (continued)**

**Ask a doctor or pharmacist before use if you are aspirin for heart attack or stroke.** Because naproxen may decrease the benefit of aspirin, taking any other drug.

**When using this product:**  

- take with food or milk if stomach upset occurs

**Stop use and ask a doctor if:**  

- you experience any of the following signs of stomach bleeding:
  - black stools
  - blood in stool
  - feeling faint
  - vomiting that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - swelling in one part or side of body
  - sudden speech
  - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- if these like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

**If pregnant or breast-feeding, ask a health professional before use.** It is especially important not to use naproxen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**  

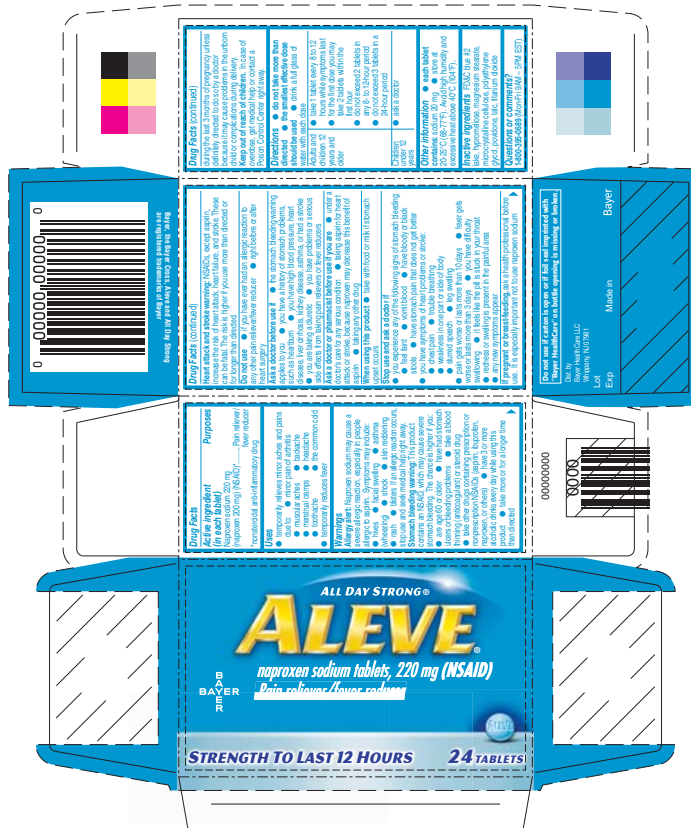
- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose
- adults and children 12 years and older: take 1 tablet every 8 to 12 hours while symptoms last
- on the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period
- children under 12 years: ask a doctor

**Other information**  

- each tablet contains: sodium 20 mg
- store at 20° to 25°C (68° to 77°F). Avoid high humidity and excessive heat above 90°F (32°C).
- Do not use if tear strip with "Bayer HealthCare" is torn or missing.

**Inactive ingredients:** FD&C Blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

**Questions?** 1-800-366-0889 (Mon-Fri 9-4 EST)



FDA00191-1

DRUG FACTS INFO:	Modified Format	Actual	IN FILE
CATEGORY	Tablet	7.1 pt	7.1 pt
Drug Facts Title	>7 pt	7.1 pt	7.1 pt
Drug Facts Content	7 pt	7 pt	7 pt
Headings*	7 pt bold italic	7 pt	7 pt
Subheadings†	<6 pt	6 pt	6 pt
Body text	<6 pt	6 pt	6 pt
Bullets	6 pt	6 pt	6 pt
Linking	<6 pt	6 pt	6 pt
Headlines	0.5 pt rule	0.5 pt	0.5 pt
Box and Barlines‡	>0.5 pt rule	2.5 pt	2.5 pt
Characters Per Inch	No more than 300	<300	<300

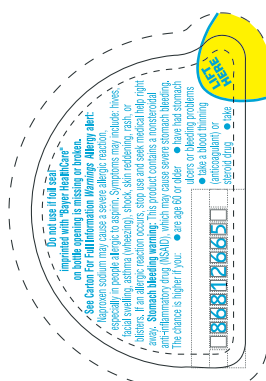
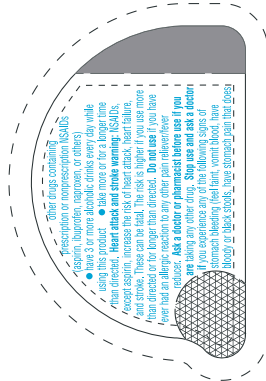
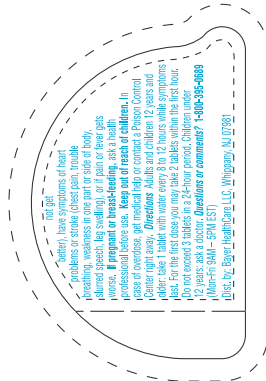
\* Headings are to be at least 6pt larger than Body Text  
 † Drug Facts Box is to be larger than all other text and used in 6pt  
 ‡ Box Barlines may be omitted and other content used to highlight Drug Facts info



200%



100%



**Do not use if foil seal is impaired with Bayer HealthCare logo, Bayer cross, or Bayer HealthCare logo.**

**See Caution for Full Information About Allergic Reactions.**

**Caution:** Aspirin sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin redness/itch, or difficulty breathing.

**Stomach Bleeding Warning:** This product causes a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is highest if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- are taking any other drug, especially if you are taking aspirin, anticoagulant or antiplatelet drug, corticosteroid, antidepressant, or alcohol

**Other drugs containing Aspirin:** Aspirin is contained in many other drugs, including combination products with acetaminophen, ibuprofen, or other pain relievers.

**Do not use if you have:**

- a prescription or nonprescription NSAID (aspirin, ibuprofen, naproxen, celecoxib, rofecoxib, etc.)
- a stomach ulcer or active or recent bleeding
- a history of asthma, hives, or other allergic reactions
- a history of heart attack, heart failure, or other heart disease
- a history of liver disease
- a history of kidney disease
- a history of alcohol abuse
- a history of surgery, especially if you are taking any other drug
- a history of stomach bleeding (red hair, vomit blood, black, sticky, blue stools), have stomach pain that lasts longer than 2 days, or have a longer time than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, or stroke. The risk may increase as you take these drugs for a longer time than directed or for longer than intended. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer. **Ask a doctor or pharmacist before use if you are taking any other drug.** Stop use and ask a doctor about stomach bleeding (red hair, vomit blood, black, sticky, blue stools), have stomach pain that lasts longer than 2 days, or have a longer time than directed.

**Do not get Aspirin on your face, eyes, or hair.**

**Do not use Aspirin if you have:**

- a prescription or nonprescription NSAID (aspirin, ibuprofen, naproxen, celecoxib, rofecoxib, etc.)
- a stomach ulcer or active or recent bleeding
- a history of asthma, hives, or other allergic reactions
- a history of heart attack, heart failure, or other heart disease
- a history of liver disease
- a history of kidney disease
- a history of alcohol abuse
- a history of surgery, especially if you are taking any other drug
- a history of stomach bleeding (red hair, vomit blood, black, sticky, blue stools), have stomach pain that lasts longer than 2 days, or have a longer time than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, or stroke. The risk may increase as you take these drugs for a longer time than directed or for longer than intended. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer. **Ask a doctor or pharmacist before use if you are taking any other drug.** Stop use and ask a doctor about stomach bleeding (red hair, vomit blood, black, sticky, blue stools), have stomach pain that lasts longer than 2 days, or have a longer time than directed.

**Do not use Aspirin if you have:**

- a prescription or nonprescription NSAID (aspirin, ibuprofen, naproxen, celecoxib, rofecoxib, etc.)
- a stomach ulcer or active or recent bleeding
- a history of asthma, hives, or other allergic reactions
- a history of heart attack, heart failure, or other heart disease
- a history of liver disease
- a history of kidney disease
- a history of alcohol abuse
- a history of surgery, especially if you are taking any other drug
- a history of stomach bleeding (red hair, vomit blood, black, sticky, blue stools), have stomach pain that lasts longer than 2 days, or have a longer time than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, or stroke. The risk may increase as you take these drugs for a longer time than directed or for longer than intended. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer. **Ask a doctor or pharmacist before use if you are taking any other drug.** Stop use and ask a doctor about stomach bleeding (red hair, vomit blood, black, sticky, blue stools), have stomach pain that lasts longer than 2 days, or have a longer time than directed.

**Do not use Aspirin if you have:**

- a prescription or nonprescription NSAID (aspirin, ibuprofen, naproxen, celecoxib, rofecoxib, etc.)
- a stomach ulcer or active or recent bleeding
- a history of asthma, hives, or other allergic reactions
- a history of heart attack, heart failure, or other heart disease
- a history of liver disease
- a history of kidney disease
- a history of alcohol abuse
- a history of surgery, especially if you are taking any other drug
- a history of stomach bleeding (red hair, vomit blood, black, sticky, blue stools), have stomach pain that lasts longer than 2 days, or have a longer time than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, or stroke. The risk may increase as you take these drugs for a longer time than directed or for longer than intended. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer. **Ask a doctor or pharmacist before use if you are taking any other drug.** Stop use and ask a doctor about stomach bleeding (red hair, vomit blood, black, sticky, blue stools), have stomach pain that lasts longer than 2 days, or have a longer time than directed.

ICL (updated 2/27/19)	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	NA
Drug Facts Continued	7 pt*	NA
Headings	7 pt-bold/italic*	4.5 pt
Subheadings	6 pt*	4.5 pt
Body Text	6 pt*	4.5 pt
Bullets	5 pt	8 pt
Headlines	0.5 pt rule	NA
Barlines†	> 0.5 pt rule	NA

Characters per inch rule is not applicable to ICL.  
 \* Minimum font size is 4.5 pt, long as ascenders and descenders do not touch.  
 † FDA recommends size 2.5 pt type.

**MADE IN THE USA**

Made in the USA  
Lot  
Exp

\*If you are not sure if your product is genuine, please refer to the packaging information for more details.

**Drug Facts**

**Active ingredient (in each tablet):** naproxen sodium (NSAID) ... pain reliever/fever reducer

**Purposes:** To temporarily relieve minor aches and pains due to:

- muscle aches
- menstrual cramps
- headaches
- toothaches
- the common cold
- minor sprains

**Uses:** To temporarily relieve minor aches and pains due to:

- muscle aches
- menstrual cramps
- headaches
- toothaches
- the common cold
- minor sprains

**Warnings:** Naproxen sodium may cause a change in sleep pattern, especially in people who take it at night. Symptoms may include difficulty sleeping. Stop taking naproxen sodium if you have any of the following symptoms:

- dizziness
- lightheadedness
- stomach pain
- skin rash
- severe dizziness
- severe stomach pain
- fainting
- severe dizziness
- severe stomach pain
- fainting

**Directions:** Take one tablet every 8 to 12 hours with each meal, with or without food, as directed on the label. Do not exceed 2 tablets in any 24-hour period unless your doctor says otherwise.

**Other information:** Each tablet contains sodium 20 mg. Use caution if you are on a sodium-restricted diet. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Contains:** 50 tablets

**Questions or comments? 1-800-538-8888**

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**ALL DAY STRONG®**

# ALEVE®

naproxen sodium tablets, 220 mg (NSAID)  
 Pain reliever/fever reducer

**STRENGTH TO LAST 12 HOURS      50 TABLETS**




FDA00193-1

DRUG FACTS INFO		
REQUIRED	ACTUAL IN FILE	
Drug Facts Title	>8 pt **	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings <sup>†</sup>	8 pt-bold italic <sup>†</sup>	8 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0.5 pt	0 pt, 0.2 pt
Horizontal lines	0.5 pt rule	0.5 pt
Box and Barlines <sup>†</sup>	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 33	≤39

<sup>†</sup> Headings are to be at least 20% larger than Body Text.  
<sup>\*\*</sup> Drug Facts Title to be larger than all other type size used in DFP.  
<sup>††</sup> FDA recommends 2.5 pt rule.

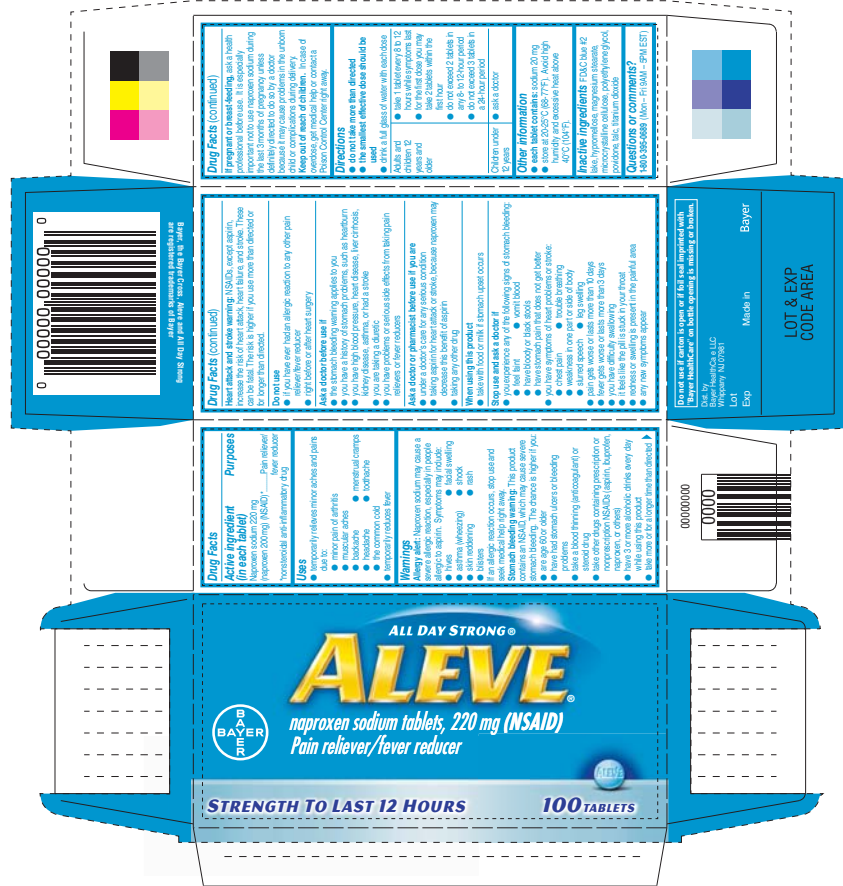


200%



100%





FDA00251-1

DRUG FACTS INFO (Updated 5/19/16)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>6 pt. <sup>1*</sup>	8.1 pt.
Drug Facts Continued	5 pt.	6 pt.
Headings <sup>2†</sup>	6 pt. bold italic <sup>3</sup>	6 pt.
Subheadings	>6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	>0.5 pt.	0.5 pt.
Horlines	0.5 pt. rule	0.5 pt.
Box and Barlines <sup>4</sup>	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 28 <sup>5</sup>	<28

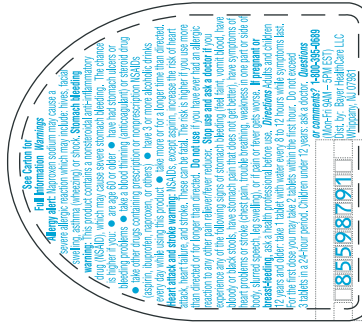
<sup>1</sup> Headings are to be at least 24pt larger than Body Text.  
<sup>2</sup> Drug Facts Title and larger than all other text size used in DPP.  
<sup>3</sup> FDA Recommends 2.5pt rule.



200%



100%



DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	-
Drug Facts Continued	8 pt.	-
Headings <sup>a</sup>	8 pt-Bold Italic <sup>b</sup>	4.5 pt.
Subheadings	>6 pt.	4.5 pt.
Body Text	>8 pt.	4.5 pt.
Bullets	5 pt.	8 pt.
Leading	>0.5 pt.	4.5 pt.
Headlines	0.5 pt rule	-
Box and Barlines†	>0.5 pt rule	-
Characters Per Inch:	No more than 39	> 39

<sup>a</sup> Headings are to be at least 6 pts larger than Body Text.  
<sup>b</sup> Drug Facts title to be larger than all other type size used in DFP.  
<sup>†</sup> FDA Recommendations 2 Color rule



**12 FREE TABLETS WITH THIS PURCHASE**


**ALL DAY STRONG®**

**ALEVE®**

naproxen sodium tablets  
0 mg (NSAID)  
Pain reliever/fever reducer

**36 TABLETS**

STRENGTH TO LAST 12 HOURS



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Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of a Bayer.

**Drug Facts (continued)**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions** ● do not take more than directed ● the smallest effective dose should be used ● drink a full glass of water with each dose

**Warnings** ● take 1 tablet every 8 to 12 hours while symptoms last ● for the first dose you may take 2 tablets within the first hour

● do not exceed 2 tablets in any 8- to 12-hour period

● do not exceed 3 tablets in a 24-hour period

● ask a doctor under 12 years

**Other information**

● contains sodium 20 mg ● store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

**Inactive ingredients** FDCC Blue #2 lake, hypromellose, magnesium stearate, polyethylene glycol, croscarmellose sodium, hydroxypropyl povidone, talc, titanium dioxide

**Questions or comments?**  
1-800-386-0889 (Mon-Fri 9-5 EST)

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Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of a Bayer.

**Drug Facts (continued)**

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Do not use** ● if you have ever had an allergic reaction to any other pain reliever/fever reducer ● right before or after heart surgery

**Ask a doctor before use if** ● the stomach bleeding warning as heartburn ● you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke ● you are taking a diuretic ● you have problems or serious side effects from taking pain relievers or fever reducers

**Ask a doctor or pharmacist before use if you are** ● under a doctor's care for any serious condition ● taking aspirin for heart attack or stroke ● taking other medicine that may decrease the benefit of aspirin ● taking other medicine that may increase the benefit of aspirin

**When using this product** ● take with food or milk if stomach upset occurs

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
- you have symptoms of heart problems or stroke:
  - chest pain or pressure
  - shortness of breath
  - weakness or dizziness
  - fainting
- you have difficulty swallowing or pain gets worse or lasts more than 10 days ● fever gets worse or lasts more than 3 days ● you have difficulty swallowing
- it feels like the pill is stuck in your throat ● redness or swelling is present in the throat area ● any new symptoms appear

**If pregnant or breastfeeding,** ask a health professional before using this product. NSAIDs may harm the fetus during the last 3 months of pregnancy, unless definitely decided to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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NO INK OR AQ

**LOT & EXP CODE AREA**

Bayer

Made in

Exp

NO INK OR AQ

DRUG FACTS INFO: (Modified Format - Updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	7.1 pt
Drug Facts Continued	7 pt	7 pt
Headings <sup>a</sup>	7 pt-bold italic <sup>b</sup>	7 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	5 pt
Leading	≥0 pt	0 - 0.2 pt
Hairlines	0.5 pt rule	0.5 pt
Box and Barlines <sup>c</sup>	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

<sup>a</sup> Headings are to be at least 2x's larger than Body Text  
<sup>b</sup> Drug Facts Title to be larger than all other type size used in DFP  
<sup>c</sup> Box, Barlines may be omitted and color contrast used to highlight Drug Facts info



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**On no use if you have:**

- been treated with aspirin, salicylates, or NSAIDs (non-steroidal anti-inflammatory drugs) within the last 6 weeks.
- been taking aspirin, salicylates, or NSAIDs for more than 30 days.
- been taking aspirin, salicylates, or NSAIDs for more than 30 days within the last 6 weeks.
- been taking aspirin, salicylates, or NSAIDs for more than 30 days within the last 6 weeks.

**See CONTRAINDICATIONS for more information.**

**Warnings:**

- **Hypertension:** Aspirin, salicylates, and NSAIDs may increase blood pressure.
- **Heart attack and stroke warning:** NSAIDs, including aspirin, may increase the risk of heart attack, heart failure, stroke, and death. Stop use and ask a doctor if you have had an allergic reaction to any other pain reliever/fever reducer.
- **Ask a doctor or pharmacist before use if you are using any other drug.** Stop use and ask a doctor if you are taking aspirin, salicylates, or NSAIDs, or if you are taking blood thinning drugs, or if you have stomach bleeding, heart, vomit, blood, or

**Other drugs containing aspirin, salicylates, or NSAIDs:**

- Aspirin
- Salicylates
- NSAIDs

**Do not use if you have:**

- been treated with aspirin, salicylates, or NSAIDs within the last 6 weeks.
- been taking aspirin, salicylates, or NSAIDs for more than 30 days.
- been taking aspirin, salicylates, or NSAIDs for more than 30 days within the last 6 weeks.

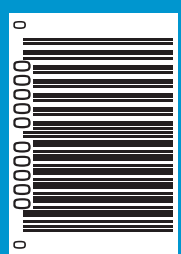
**See CONTRAINDICATIONS for more information.**

**Warnings:**

- **Hypertension:** Aspirin, salicylates, and NSAIDs may increase blood pressure.
- **Heart attack and stroke warning:** NSAIDs, including aspirin, may increase the risk of heart attack, heart failure, stroke, and death. Stop use and ask a doctor if you have had an allergic reaction to any other pain reliever/fever reducer.
- **Ask a doctor or pharmacist before use if you are using any other drug.** Stop use and ask a doctor if you are taking aspirin, salicylates, or NSAIDs, or if you are taking blood thinning drugs, or if you have stomach bleeding, heart, vomit, blood, or

ICL (updated 2/27/19)	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	NA
Drug Facts Continued	7 pt*	NA
Headings	7 pt-bold italic*	4.5 pt
Subheadings	6 pt*	4.5 pt
Body Text	6 pt*	4.5 pt
Bullet	5 pt	8 pt
Headlines	0.5 pt rule	NA
Barlines†	> 0.5 pt rule	NA

Characters per inch rule is not applicable to ICL.  
\*Minimum font size is 4.5 pt, long as ascenders and descenders do not touch.  
† FDA recommends size 2.5 pt type.



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**Drug Facts (continued)**

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever or fever reducer
- right before or after heart surgery

**Ask a doctor before use if:**

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heart burn or acid reflux
- you have high blood pressure, heart disease, liver or kidney disease, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

**Ask a doctor or pharmacist before use if you are:**

- under a doctor's care for any serious condition
- pregnant, trying to get pregnant, or breastfeeding
- depressed or taking any other drug

**When using this product:**

- take with food or milk if stomach upset occurs

**Stop use and ask a doctor if:**

- you experience any of the following signs of stomach bleeding:
  - black, tarry stools
  - blood in vomit or stool
  - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - swelling of the face, legs, or body
  - slurred speech
- your pain gets worse or lasts more than 10 days
- your fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- you have a rash or hives
- any new symptoms appear

Do not use if carbon is open or if foil seal imprinted with "Bayer Healthcare" on bottle opening is missing or broken.

Dist. by:  
Bayer HealthCare LLC  
Whispery, NJ 07081

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Made in  
Bayer

**Drug Facts**

**Active ingredient**  
(in each tablet)  
Naproxen sodium 220 mg (NSAID)<sup>1</sup>..... Pain reliever/  
fever reducer  
<sup>2</sup>Nonsteroidal anti-inflammatory drug

**Uses**

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - backache
  - headache
  - menstrual cramps
  - toothache
  - the common cold
- temporarily reduces fever

**Warnings**

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- swelling of the face, lips, tongue, or throat
- skin rash (hives)
- facial swelling
- itching
- skin redness
- itch
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product may cause stomach bleeding. The chance of stomach bleeding is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or antiplatelet drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day
- take more or for a longer time than directed

**Drug Facts (continued)**

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These risks may be higher if you use more than directed or for longer than directed.

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever or fever reducer
- right before or after heart surgery

**Ask a doctor before use if:**

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heart burn or acid reflux
- you have high blood pressure, heart disease, liver or kidney disease, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

**Ask a doctor or pharmacist before use if you are:**

- under a doctor's care for any serious condition
- pregnant, trying to get pregnant, or breastfeeding
- depressed or taking any other drug

**When using this product:**

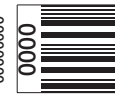
- take with food or milk if stomach upset occurs

**Stop use and ask a doctor if:**

- you experience any of the following signs of stomach bleeding:
  - black, tarry stools
  - blood in vomit or stool
  - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - swelling of the face, legs, or body
  - slurred speech
- your pain gets worse or lasts more than 10 days
- your fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- you have a rash or hives
- any new symptoms appear

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**15 FREE TABLETS WITH THIS PURCHASE**

**ALL DAY STRONG®**

**ALEVE®**

naproxen sodium tablets, 220 mg (NSAID)<sup>1</sup>

Pain reliever/fever reducer

**65 TABLETS**

**STRENGTH TO LAST 12 HOURS**

FDA00185-1

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt <sup>14</sup>	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings*	8 pt-bold italic <sup>15</sup>	8 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0.5 pt	0 pt
Hairlines	0.5 pt rule	0.5 pt
Box and Barlines†	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	<39

<sup>14</sup> Headings are to be at least 2pts larger than Body Text.  
<sup>15</sup> Drug Facts Title to be larger than all other type size used in DFP.  
† FDA Recommends 2.5pt rule



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DRUG FACTS INFO: (Modified Format)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	-
Drug Facts Continued	7 pt	-
Headings*	7 pt- <b>bold italic</b> *	4.5 pt
Subheadings	≥6 pt	4.5 pt
Body Text	≥6 pt	4.5 pt
Bullets	5 pt	8 pt
Leading	≥0 pt	4.5 pt
Hairlines	0.5 pt rule	-
Box and Barlines†	>0.5 pt. rule	-
Characters Per Inch:	No more than 39	> 39
<small>* Headings are to be at least 2pts larger than Body Text.                      † Drug Facts Title to be larger than all other type size used in DFP                      ‡ Box Barline may be omitted and color contrast used to highlight Drug Facts Info</small>		

**50 FREE TABLETS WITH THIS PURCHASE**  
**150 TABLETS**  
**STRENGTH TO LAST 12 HOURS**  
**ALL DAY STRONG®**  
**ALEVE®**  
naproxen sodium tablets 250 mg  
**Pain relief/fever reducer**

**Warnings**  
Aleve® (naproxen sodium) may cause a severe allergic reaction, possibly leading to anaphylaxis. Symptoms may include hives, rash, itching, swelling, especially of the face, tongue, or throat, dizziness, difficulty breathing, wheezing, or asthma. If you experience any of the following signs of stomach bleeding, stop use with food or milk, a stomach upset occurs, you experience any of the following signs of stomach bleeding: heartburn, indigestion, or stomach pain, or you see blood or black stools in your stool, stop use with food or milk, a stomach upset occurs, or you experience any of the following signs of stomach bleeding: heartburn, indigestion, or stomach pain, or you see blood or black stools in your stool.

**Directions**  
Take 1 or 2 tablets with food or milk, a stomach upset occurs, or you experience any of the following signs of stomach bleeding: heartburn, indigestion, or stomach pain, or you see blood or black stools in your stool.

**Drug Facts (continued)**  
Ask a doctor before use if:  
● you are pregnant or suspect you are pregnant. You should stop use if you become pregnant.  
● you are breastfeeding or plan to breastfeed.  
● you have a history of stomach problems, heart disease, liver disease, kidney disease, asthma, or high blood pressure.  
● you have a history of asthma, hives, or other allergic reactions.  
● you have a history of stomach problems, such as heartburn, indigestion, or stomach pain.  
● you are taking a blood thinner or aspirin.  
● you are taking a diuretic.  
● you have had an allergic reaction to any other pain reliever or nonsteroidal anti-inflammatory drug.

**Other Information**  
Keep out of reach of children. This product contains sodium. Do not use if the seal is broken or the container is damaged. Each tablet contains 250 mg naproxen sodium and 25 mg of hydroxypropyl methylcellulose (HPMC).

**Questions or comments?**  
1-800-992-9993 (Mon - Fri 9AM - 5PM EST)  
Bayer HealthCare, Inc., Whippany, NJ 07981  
Exp. Date: 12/31/2022  
Made in the USA

FDA00188-1

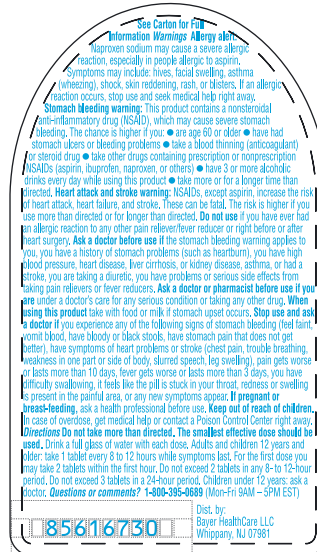
DRUG FACTS LABEL	REMOVED	APPROVAL DATE
Drug Facts	3/21/17	3/21/17
Warnings	8/27/17	8/27/17
Directions	8/27/17	8/27/17
Other Information	8/27/17	8/27/17
Questions or comments?	8/27/17	8/27/17
Illustration of the Product	8/27/17	8/27/17
Instructions for Use	8/27/17	8/27/17
Chemical Name	8/27/17	8/27/17
Strength	8/27/17	8/27/17
Manufacturer	8/27/17	8/27/17
Product Name	8/27/17	8/27/17
Product Code	8/27/17	8/27/17
Product Type	8/27/17	8/27/17
Product Description	8/27/17	8/27/17
Product Labeling	8/27/17	8/27/17
Product Illustration	8/27/17	8/27/17
Product Image	8/27/17	8/27/17
Product Photo	8/27/17	8/27/17
Product Video	8/27/17	8/27/17
Product Audio	8/27/17	8/27/17
Product Animation	8/27/17	8/27/17
Product Illustration	8/27/17	8/27/17
Product Image	8/27/17	8/27/17
Product Photo	8/27/17	8/27/17
Product Video	8/27/17	8/27/17
Product Audio	8/27/17	8/27/17
Product Animation	8/27/17	8/27/17
Product Illustration	8/27/17	8/27/17
Product Image	8/27/17	8/27/17
Product Photo	8/27/17	8/27/17
Product Video	8/27/17	8/27/17
Product Audio	8/27/17	8/27/17
Product Animation	8/27/17	8/27/17
Product Illustration	8/27/17	8/27/17
Product Image	8/27/17	8/27/17
Product Photo	8/27/17	8/27/17
Product Video	8/27/17	8/27/17
Product Audio	8/27/17	8/27/17
Product Animation	8/27/17	8/27/17



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DRUG FACTS INFO: (Modified Format)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	-
Drug Facts Continued	7 pt	-
Headings*	7 pt- <b>bold italic</b> *	4.5 pt
Subheadings	≥6 pt	4.5 pt
Body Text	≥6 pt	4.5 pt
Bullets	5 pt	8 pt
Leading	≥0 pt	4.5 pt
Hairlines	0.5 pt rule	-
Box and Barlines†	>0.5 pt. rule	-
Characters Per Inch:	No more than 39	> 39
<small>* Headings are to be at least 2pts larger than Body Text.                      ** Drug Facts Title to be larger than all other type size used in DFP                      † Box Barline may be omitted and color contrast used to highlight Drug Facts Info</small>		

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**Do not use this product if "Bayer Healthcare" under caps is torn or missing.**

**LOT**

**Drug Facts**

**Active Ingredient (in each tablet)**

**Hydrocodone bitartrate** (as the bitartrate salt) 2.5 mg  
**Paracetamol** 325 mg

Paracetamol (Acetaminophen) is a pain reducer.

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**Drug Facts (continued)**

**Important information:** Use as directed. Do not use more than directed. Do not use if you are pregnant or breastfeeding. See a health professional before use. It is especially important not to use magnesium sodium citrate during pregnancy because it may cause problems in the unborn child or during birth. Do not use if pregnant or breastfeeding unless otherwise directed. Do not use if you have had an allergic reaction to any of the ingredients listed in this product, or if you have had an allergic reaction to any other product containing aspirin, salicylates, or salicylic acid.

**Warnings**

- Do not take more than directed.
- Do not take more than 4 tablets in 24 hours.
- Do not take more than 2 tablets in any 8-hour period.
- Do not take more than 12 tablets in 24 hours.
- Do not take more than 12 tablets in any 24-hour period.

**Directions**

- Take 1 tablet every 6 to 12 hours as needed for pain relief. Do not exceed the recommended dosage.
- Take 2 tablets every 6 to 12 hours for the first 48 hours after surgery. Do not exceed the recommended dosage.
- Take 2 tablets every 6 to 12 hours for the first 48 hours after surgery. Do not exceed the recommended dosage.

**Other Information**

- Each tablet contains sodium 20 mg.
- Keep out of reach of children.
- Store at 20° to 25°C (68° to 77°F). Avoid high humidity and excessive moisture.

**How to use:** Take 1 tablet every 6 to 12 hours as needed for pain relief. Do not exceed the recommended dosage.

**Questions or comments?** Call 1-800-398-6899 (Toll-free).

**LOT**

**EXP.**

**MADE IN**

**Bayer**

Dist. by: Bayer Healthcare LLC  
 Whippany, NJ 07981  
 Bayer, the Bayer Cross, Aspirin and Hydrocodone are registered trademarks of Bayer.

**Drug Facts (continued)**

**Use:** Temporarily relieve minor aches and pains due to: headache, toothache, muscle aches, minor pain of arthritis, neuralgia, migraine, menstrual cramps, and other minor pains.

**Warnings:** Magnesium sodium citrate may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: skin rash, hives, swelling of the face or throat, difficulty breathing, dizziness, fainting, or a severe allergic reaction. Do not use if you have had a severe allergic reaction to any other product containing aspirin, salicylates, or salicylic acid.

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These risks may be higher if you use more than directed or for a long time.

**Do not use:** Do not use if you have had an allergic reaction to any other product containing aspirin, salicylates, or salicylic acid.

**Take a doctor's warning:** This product contains an NSAID. NSAIDs can cause stomach bleeding. This bleeding may be fatal. Do not use if you are taking any other drug containing aspirin, salicylates, or salicylic acid.

**Do not take more than directed:** Do not take more than directed. Do not take more than 4 tablets in 24 hours. Do not take more than 2 tablets in any 8-hour period. Do not take more than 12 tablets in 24 hours. Do not take more than 12 tablets in any 24-hour period.

Category	Strength	Actual in Package
Drug Facts Table	3.1 g	3.1 g
Drug Facts Orange	3.1 g	3.1 g
Drug Facts White	3.1 g	3.1 g
Samples	3.1 g	3.1 g
Drug Facts	3.1 g	3.1 g
Other	3.1 g	3.1 g
Not Reported	3.1 g	3.1 g
Other	3.1 g	3.1 g

\*Hydrocodone bitartrate, paracetamol (acetaminophen), and aspirin are active ingredients.

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100%



Actual Size 100%





200%



100%

**Do not use this product if "Bayer HealthCare" under caps is torn or missing.**

**OPEN TO READ DRUG FACTS BEFORE USE**

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EXP.

**Drug Facts**

**Important Information:**  
 • Keep out of reach of children.  
 • If you are pregnant, may become pregnant, or are breastfeeding, ask your healthcare provider about the risks and benefits of using this product.  
 • Tell your healthcare provider if you are taking or plan to take other drugs, including over-the-counter drugs, vitamins, or supplements.  
 • Tell your healthcare provider if you have ever had an allergic reaction to any other pain reliever, or if you have asthma, kidney disease, or stomach ulcers.

**Warnings:**  
 • **Heart Attack and Stroke Warnings:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These risks may increase when you take these drugs for a long time, at higher doses, or when you use them together with other drugs.  
 • **Bleeding Warnings:** NSAIDs, except aspirin, may increase the risk of bleeding, which may be fatal. Tell your doctor or pharmacist if you are taking or plan to take other drugs that may increase the risk of bleeding, such as aspirin, blood thinners, or anti-clotting drugs.  
 • **Stomach Ulcers and Bleeding:** NSAIDs, except aspirin, may cause stomach ulcers and bleeding, which may be fatal.  
 • **Heart Failure:** NSAIDs, except aspirin, may cause or worsen heart failure.  
 • **Fluid Retention and Blood Pressure:** NSAIDs, except aspirin, may cause or worsen fluid retention and high blood pressure.  
 • **Kidney Disease:** NSAIDs, except aspirin, may cause or worsen kidney disease.  
 • **Liver and Stomach Problems:** NSAIDs, except aspirin, may cause or worsen liver and stomach problems.  
 • **Low Blood Counts:** NSAIDs, except aspirin, may cause or worsen low blood counts, which may lead to anemia, bleeding, or infection.  
 • **Hypertension:** NSAIDs, except aspirin, may cause or worsen high blood pressure.  
 • **Dehydration:** NSAIDs, except aspirin, may cause or worsen dehydration, which may lead to kidney failure or other complications.  
 • **Respiratory Problems:** NSAIDs, except aspirin, may cause or worsen asthma or other respiratory problems.  
 • **Alcohol:** NSAIDs, except aspirin, may cause or worsen stomach bleeding, ulcers, and liver damage when used with alcohol.

**Directions:**  
 • **Do not take more than directed.**  
 • **The risk of serious side effects is higher if you take these drugs for a long time, at higher doses, or when you use them together with other drugs.**  
 • **Do not take these drugs if you have ever had an allergic reaction to any other pain reliever, or if you have asthma, kidney disease, or stomach ulcers.**  
 • **Do not take these drugs if you are pregnant, may become pregnant, or are breastfeeding, unless your healthcare provider tells you to.**  
 • **Do not take these drugs if you have ever had a stomach ulcer or bleeding, or if you have kidney disease, heart failure, or high blood pressure.**  
 • **Do not take these drugs if you have ever had liver or stomach problems.**  
 • **Do not take these drugs if you have ever had low blood counts, which may lead to anemia, bleeding, or infection.**  
 • **Do not take these drugs if you have ever had high blood pressure.**  
 • **Do not take these drugs if you have ever had dehydration, which may lead to kidney failure or other complications.**  
 • **Do not take these drugs if you have ever had asthma or other respiratory problems.**  
 • **Do not take these drugs if you have ever had stomach bleeding, ulcers, or liver damage when used with alcohol.**

**Other Information:**  
 • Each tablet contains sodium 20 mg.  
 • Contains 60 tablets in a bottle.  
 • Store at room temperature (20° to 25°C (68° to 77°F)).  
 • Keep out of reach of children.  
 • If you are pregnant, may become pregnant, or are breastfeeding, ask your healthcare provider about the risks and benefits of using this product.  
 • Tell your healthcare provider if you are taking or plan to take other drugs, including over-the-counter drugs, vitamins, or supplements.  
 • Tell your healthcare provider if you have ever had an allergic reaction to any other pain reliever, or if you have asthma, kidney disease, or stomach ulcers.

**Questions or comments?** 1-800-368-8888  
 (For more information, visit [www.bayer.com](http://www.bayer.com).)

**Drug Facts (continued)**

**Drug Facts (continued)**

**Warnings:**

- Heart attack and stroke warnings: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These risks may increase when you take these drugs for a long time, at higher doses, or when you use them together with other drugs.
- Bleeding warnings: NSAIDs, except aspirin, may increase the risk of bleeding, which may be fatal. Tell your doctor or pharmacist if you are taking or plan to take other drugs that may increase the risk of bleeding, such as aspirin, blood thinners, or anti-clotting drugs.
- Stomach ulcers and bleeding: NSAIDs, except aspirin, may cause stomach ulcers and bleeding, which may be fatal.
- Heart failure: NSAIDs, except aspirin, may cause or worsen heart failure.
- Fluid retention and blood pressure: NSAIDs, except aspirin, may cause or worsen fluid retention and high blood pressure.
- Kidney disease: NSAIDs, except aspirin, may cause or worsen kidney disease.
- Liver and stomach problems: NSAIDs, except aspirin, may cause or worsen liver and stomach problems.
- Low blood counts: NSAIDs, except aspirin, may cause or worsen low blood counts, which may lead to anemia, bleeding, or infection.
- Hypertension: NSAIDs, except aspirin, may cause or worsen high blood pressure.
- Dehydration: NSAIDs, except aspirin, may cause or worsen dehydration, which may lead to kidney failure or other complications.
- Respiratory problems: NSAIDs, except aspirin, may cause or worsen asthma or other respiratory problems.
- Alcohol: NSAIDs, except aspirin, may cause or worsen stomach bleeding, ulcers, and liver damage when used with alcohol.

**Directions:**

- Do not take more than directed.
- The risk of serious side effects is higher if you take these drugs for a long time, at higher doses, or when you use them together with other drugs.
- Do not take these drugs if you have ever had an allergic reaction to any other pain reliever, or if you have asthma, kidney disease, or stomach ulcers.
- Do not take these drugs if you are pregnant, may become pregnant, or are breastfeeding, unless your healthcare provider tells you to.
- Do not take these drugs if you have ever had a stomach ulcer or bleeding, or if you have kidney disease, heart failure, or high blood pressure.
- Do not take these drugs if you have ever had liver or stomach problems.
- Do not take these drugs if you have ever had low blood counts, which may lead to anemia, bleeding, or infection.
- Do not take these drugs if you have ever had high blood pressure.
- Do not take these drugs if you have ever had dehydration, which may lead to kidney failure or other complications.
- Do not take these drugs if you have ever had asthma or other respiratory problems.
- Do not take these drugs if you have ever had stomach bleeding, ulcers, or liver damage when used with alcohol.

**Other Information:**

- Each tablet contains sodium 20 mg.
- Contains 60 tablets in a bottle.
- Store at room temperature (20° to 25°C (68° to 77°F)).
- Keep out of reach of children.
- If you are pregnant, may become pregnant, or are breastfeeding, ask your healthcare provider about the risks and benefits of using this product.
- Tell your healthcare provider if you are taking or plan to take other drugs, including over-the-counter drugs, vitamins, or supplements.
- Tell your healthcare provider if you have ever had an allergic reaction to any other pain reliever, or if you have asthma, kidney disease, or stomach ulcers.

**Questions or comments?** 1-800-368-8888  
 (For more information, visit [www.bayer.com](http://www.bayer.com).)

**Drug Facts (continued)**

**LOT**

**EXP.**

**MADE IN**

**Bayer**

Dist. by:  
 Bayer Healthcare LLC  
 Whippany, NJ 07981  
 Bayer, the Bayer Cross, Aleve and  
 Advil are registered  
 trademarks of Bayer.

**Drug Facts (continued)**

**Warnings:**

- Heart attack and stroke warnings: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These risks may increase when you take these drugs for a long time, at higher doses, or when you use them together with other drugs.
- Bleeding warnings: NSAIDs, except aspirin, may increase the risk of bleeding, which may be fatal. Tell your doctor or pharmacist if you are taking or plan to take other drugs that may increase the risk of bleeding, such as aspirin, blood thinners, or anti-clotting drugs.
- Stomach ulcers and bleeding: NSAIDs, except aspirin, may cause stomach ulcers and bleeding, which may be fatal.
- Heart failure: NSAIDs, except aspirin, may cause or worsen heart failure.
- Fluid retention and blood pressure: NSAIDs, except aspirin, may cause or worsen fluid retention and high blood pressure.
- Kidney disease: NSAIDs, except aspirin, may cause or worsen kidney disease.
- Liver and stomach problems: NSAIDs, except aspirin, may cause or worsen liver and stomach problems.
- Low blood counts: NSAIDs, except aspirin, may cause or worsen low blood counts, which may lead to anemia, bleeding, or infection.
- Hypertension: NSAIDs, except aspirin, may cause or worsen high blood pressure.
- Dehydration: NSAIDs, except aspirin, may cause or worsen dehydration, which may lead to kidney failure or other complications.
- Respiratory problems: NSAIDs, except aspirin, may cause or worsen asthma or other respiratory problems.
- Alcohol: NSAIDs, except aspirin, may cause or worsen stomach bleeding, ulcers, and liver damage when used with alcohol.

**Directions:**

- Do not take more than directed.
- The risk of serious side effects is higher if you take these drugs for a long time, at higher doses, or when you use them together with other drugs.
- Do not take these drugs if you have ever had an allergic reaction to any other pain reliever, or if you have asthma, kidney disease, or stomach ulcers.
- Do not take these drugs if you are pregnant, may become pregnant, or are breastfeeding, unless your healthcare provider tells you to.
- Do not take these drugs if you have ever had a stomach ulcer or bleeding, or if you have kidney disease, heart failure, or high blood pressure.
- Do not take these drugs if you have ever had liver or stomach problems.
- Do not take these drugs if you have ever had low blood counts, which may lead to anemia, bleeding, or infection.
- Do not take these drugs if you have ever had high blood pressure.
- Do not take these drugs if you have ever had dehydration, which may lead to kidney failure or other complications.
- Do not take these drugs if you have ever had asthma or other respiratory problems.
- Do not take these drugs if you have ever had stomach bleeding, ulcers, or liver damage when used with alcohol.

**Other Information:**

- Each tablet contains sodium 20 mg.
- Contains 60 tablets in a bottle.
- Store at room temperature (20° to 25°C (68° to 77°F)).
- Keep out of reach of children.
- If you are pregnant, may become pregnant, or are breastfeeding, ask your healthcare provider about the risks and benefits of using this product.
- Tell your healthcare provider if you are taking or plan to take other drugs, including over-the-counter drugs, vitamins, or supplements.
- Tell your healthcare provider if you have ever had an allergic reaction to any other pain reliever, or if you have asthma, kidney disease, or stomach ulcers.

**Questions or comments?** 1-800-368-8888  
 (For more information, visit [www.bayer.com](http://www.bayer.com).)

**Drug Facts (continued)**

**DRUG FACTS INFO** (continued)

CATEGORY	APPROVED	ACTUAL IN USE
Drug Facts Title	8 pt	8 1/2 pt
Drug Facts Content	8 pt	8 1/2 pt
Headings	8 pt	8 1/2 pt
Subheadings	8 pt	8 1/2 pt
Text	8 pt	8 1/2 pt
Images	8 pt	8 1/2 pt
Box and Brand Name	2 1/2 pt	2 1/2 pt
Chemical Name	8 pt	8 1/2 pt

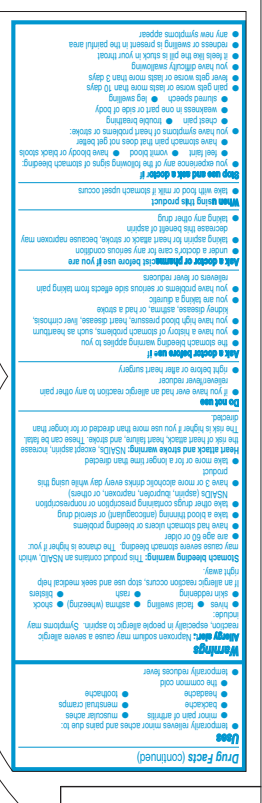
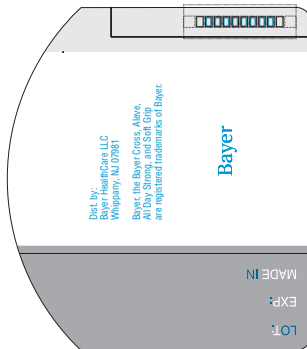
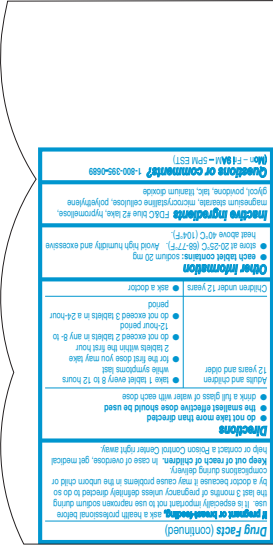
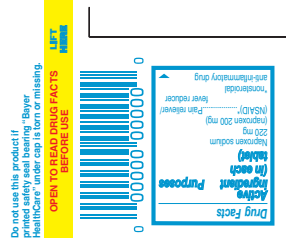
\*Hypertension risk increased for patients taking these drugs with other drugs that increase blood pressure.



200%



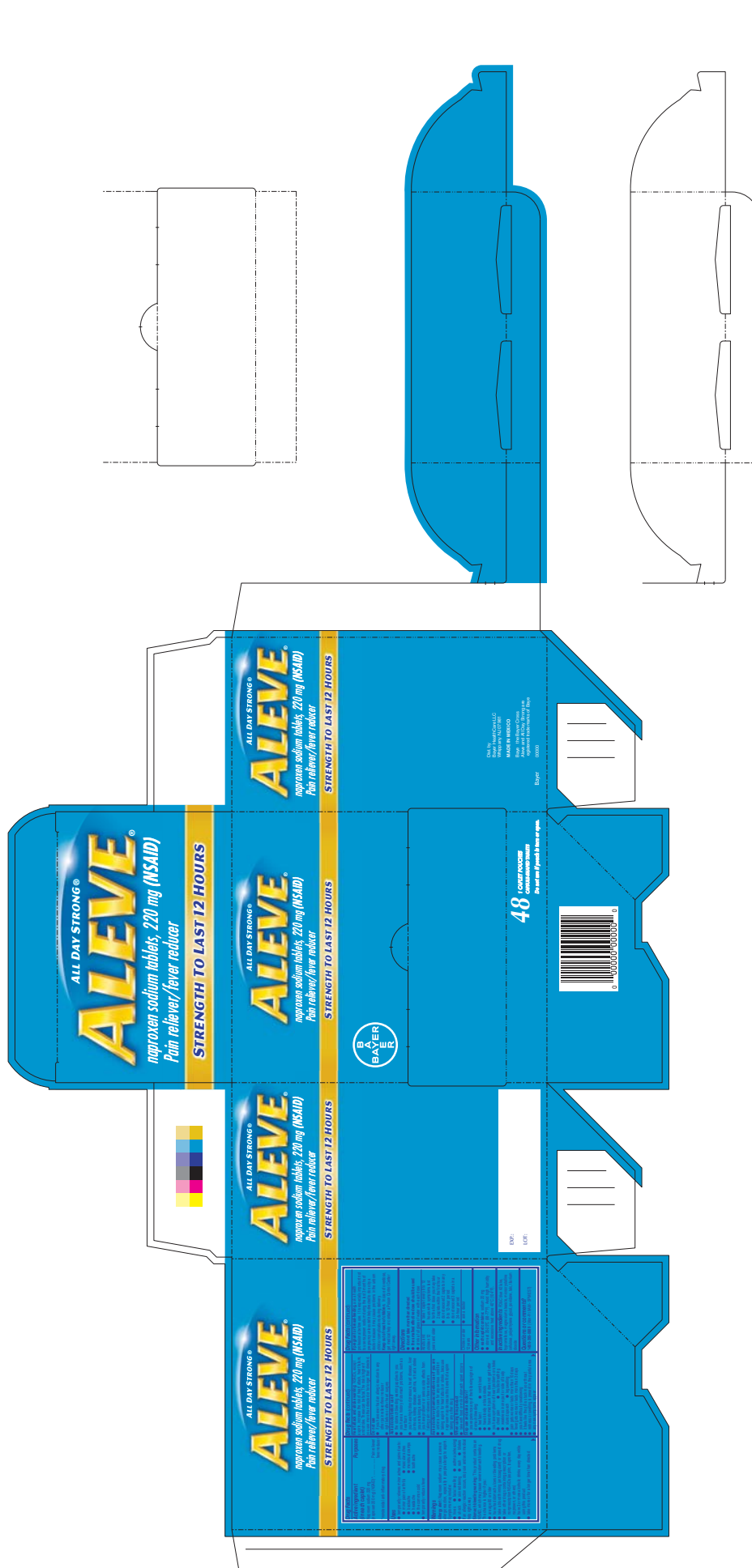
100%



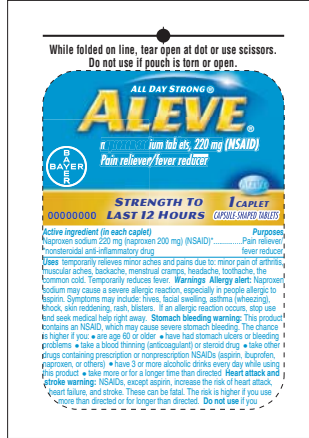
FDAA00170-1

DRUG FACTS INFO (years 1-19)	REQUIRED	ACTUAL IN FILE
Category	8.1 pt.	8.1 pt.
Drug Facts Title	8.5 pt.	8.5 pt.
Drug Facts Content	8 pt.	8 pt.
Header <sup>1</sup>	8 pt.	8 pt.
Subheader <sup>1</sup>	6 pt.	6 pt.
Body Text	6 pt.	6 pt.
Images	5 pt.	5 pt.
Warnings	30.5 pt.	30.5 pt.
Directions	30.5 pt.	30.5 pt.
Other Information	2.5 pt.	2.5 pt.
Chemical Name	2.5 pt.	2.5 pt.
Strength	2.5 pt.	2.5 pt.
Formulation	2.5 pt.	2.5 pt.
Manufacturer	2.5 pt.	2.5 pt.

<sup>1</sup> Drug Facts title to be placed above the drug facts box. <sup>2</sup> Drug Facts title to be placed above the drug facts box. <sup>3</sup> Drug Facts title to be placed above the drug facts box. <sup>4</sup> Drug Facts title to be placed above the drug facts box. <sup>5</sup> Drug Facts title to be placed above the drug facts box.



Color	CMYK	RGB
White	0,0,0,0	255,255,255
Black	0,0,0,100	0,0,0
Blue	0,0,100,0	0,0,255
Yellow	0,100,0,0	255,255,0
Magenta	100,0,0,0	255,0,255
Cyan	0,100,100,0	0,255,255
Red	100,0,100,0	255,0,0
Green	0,100,100,100	0,255,0
Grey	50,50,50,50	128,128,128
Light Grey	40,40,40,40	160,160,160
Dark Grey	60,60,60,60	100,100,100
Light Blue	0,0,100,100	0,255,255
Light Yellow	0,100,0,0	255,255,0
Light Magenta	100,0,0,0	255,0,255
Light Cyan	0,100,100,0	0,255,255
Light Red	100,0,100,0	255,0,0
Light Green	0,100,100,100	0,255,0
Light Grey	50,50,50,50	128,128,128
Light Blue	0,0,100,100	0,255,255
Light Yellow	0,100,0,0	255,255,0
Light Magenta	100,0,0,0	255,0,255
Light Cyan	0,100,100,0	0,255,255
Light Red	100,0,100,0	255,0,0
Light Green	0,100,100,100	0,255,0
Light Grey	50,50,50,50	128,128,128



FDA00224-2

ICL (updated 2/2/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	-
Drug Facts Continued	7 pt*	-
Headings	7 pt-bold italic <sup>†</sup>	4.5 pt
Subheadings	6 pt*	4.5 pt
Body Text	6 pt*	4.5 pt
Bullets	5 pt	5.5 pt
Hairlines	0.5 pt rule	-
Barlines <sup>‡</sup>	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.  
 \*ICL minimum font size is 4.5 pt.  
 † < 0.5 pt leading may be used as long as ascenders and descenders do not touch.  
 ‡ FDA recommends size 2.5 pt type

X |

never had an allergic reaction to any other pain reliever/fever reducer, or right before or after heart surgery. **Ask a doctor before use if** • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke • you are taking a diuretic • you have problems or serious side effects from taking pain relievers or fever reducers **Ask a doctor or pharmacist before use if you are** • under a doctor's care for any serious condition • taking aspirin for heart attack or stroke, because aspirin may decrease the benefit of aspirin • taking any other drug. **When using this product** take with food or milk if stomach upset occurs. **Stop use and ask a doctor if** • you experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better) • you have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling) • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • you have difficulty swallowing • it feels like the pill is stuck in your throat • redness or swelling is present in the painful area • any new symptoms appear **If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions** Do not take more than directed. The smallest effective dose should be used. Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 caplet every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 5 caplets in any 8- to 12-hour period. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor. **Other information** Each caplet contains: naproxen 275 mg. Store at 20° to 25° (68° to 77°). Avoid high humidity and excessive heat above 40°C (104°F). **Inactive ingredients** FD&C Blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide. **Questions or comments?** 1-800-365-6689 (Mon-Fri 9AM-5PM EST)  
 Dist. by: Bayer HealthCare LLC      MADE IN MEXICO  
 Whippany, NJ 07981                      00000000



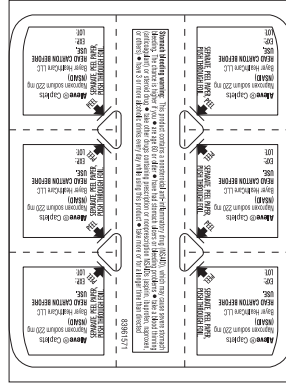
FDA00223-2

ICL (updated 2/2/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	-
Drug Facts Continued	7 pt*	-
Headings	7 pt-bold italic*	4.5 pt
Subheadings	6 pt*	4.5 pt
Body Text	6 pt*	4.5 pt
Bullets	5 pt	5.5 pt
Hairlines	0.5 pt rule	-
Barlines <sup>1</sup>	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.  
 \*ICL minimum font size is 4.5 pt.  
 < 0.5 pt. leading may be used as long as ascenders and descenders do not touch.  
<sup>1</sup> FDA recommends size 2.5 pt type



100%



ORGAN WARNING COPY POSITION

DFL

Art Production		DRUG FACTS INFO.	
CATEGORY	PRIMARY PRODUCTION REQUIRED	SECONDARY PRODUCTION REQUIRED	ACTUAL IN FILE
Drug Facts Title:	N/A	>8.0 pt	-
Drug Facts (Continued):	N/A	8 pt	-
Headings:	N/A	8 pt	-
Subheadings:	N/A	6 pt	4.5 pt
Text:	N/A	6 pt	4.5 pt
Bullets:	N/A	5 pt (no lamp)	-
Leading:	N/A	+0.5 pt	4.75 pt
Characters Per Inch:	N/A	No more than 39	39

ORGAN WARNING

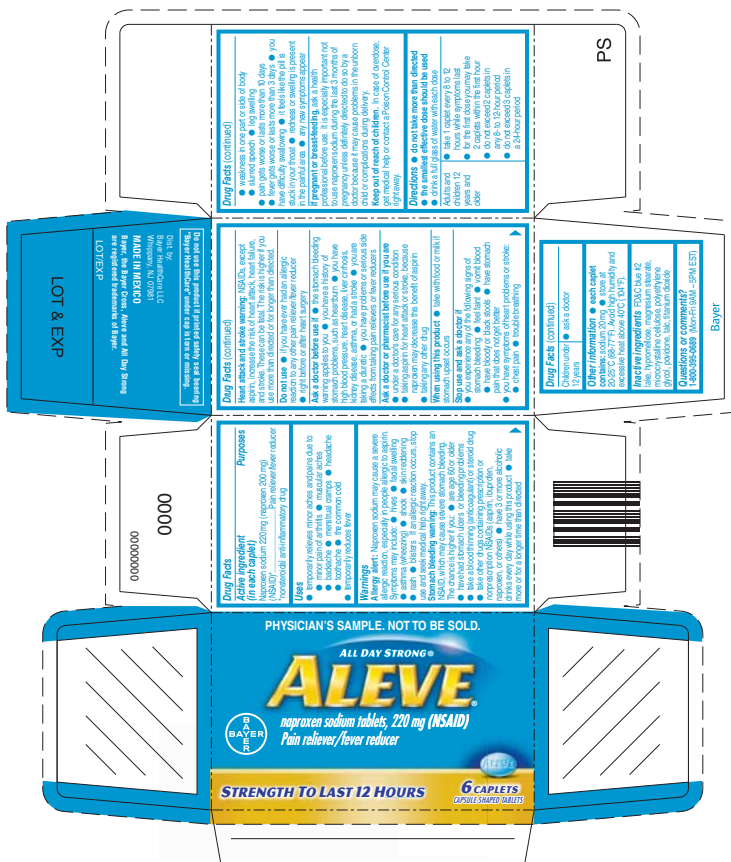
Art Production		DRUG FACTS INFO.	
CATEGORY	PRIMARY PRODUCTION REQUIRED	SECONDARY PRODUCTION REQUIRED	ACTUAL IN FILE
Drug Facts Title:	N/A	>8.0 pt	-
Drug Facts (Continued):	N/A	8 pt	-
Headings:	N/A	8 pt	-
Subheadings:	N/A	6 pt	4.5 pt
Text:	N/A	6 pt	4.5 pt
Bullets:	N/A	5 pt (no lamp)	4 pt
Leading:	N/A	+0.5 pt	4.5 pt
Characters Per Inch:	N/A	No more than 39	50

150% READ ONLY

**Strength Warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID) which may cause severe stomach bleeding. The chance of bleeding is greater if you are age 60 or older, have had stomach ulcers or bleeding problems, take a blood thinner (anticoagulant) or steroid drug, take other drugs containing prescription or nonprescription (NSAIDs), (aspirin, ibuprofen, naproxen, or others), have 3 or more alcoholic drinks every day while using this product, use more or for a longer time than directed.

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FDA00226-2

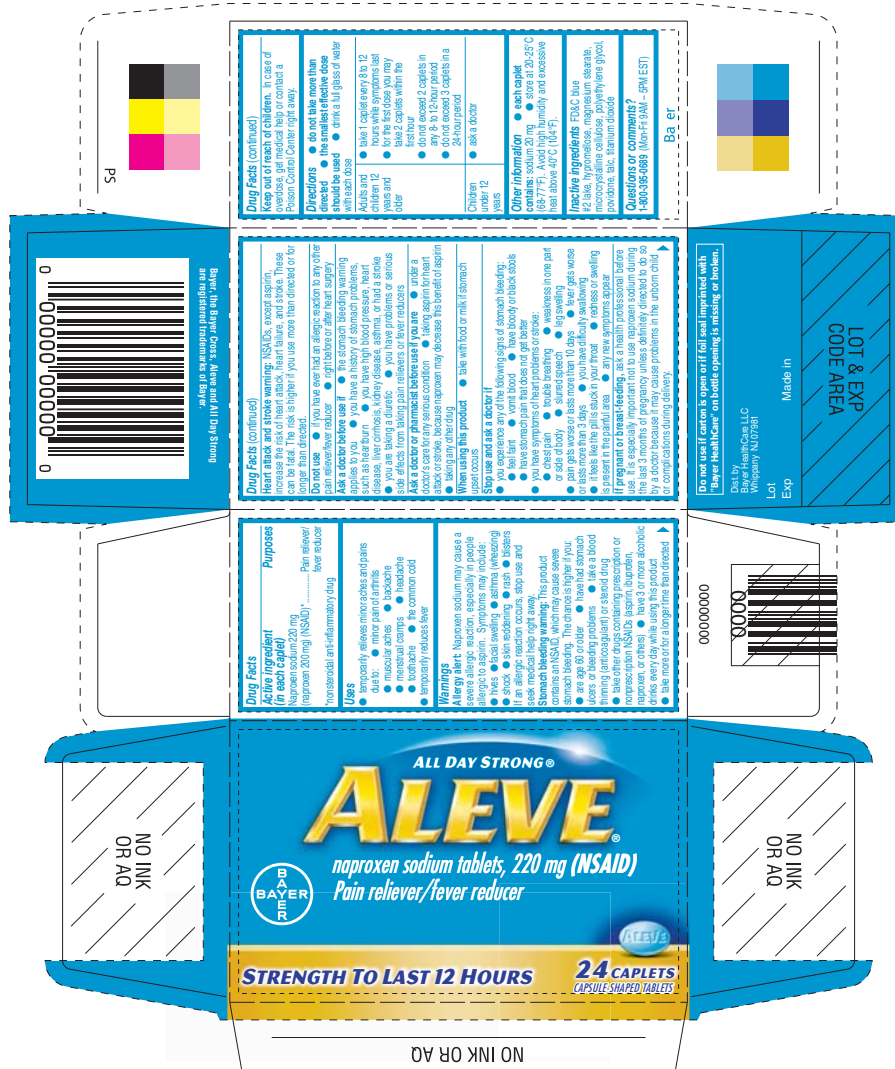
DRUG FACTS INFO: Modified Format - updated 5/13/11		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt.	7.1 pt.
Drug Facts Continued	7 pt.	7 pt.
Headings*	7 pt.-bold italic†	7 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	6 pt.	12 pt.
Leadings	≥10 pt.	10, 10.2 pt.
Headlines	0.5 pt rule	0.5 pt.
Box and Barline†	≥0.5 pt rule	2.5 pt.
Characters Per Inch	No more than 39	≤39

\*Headings are to be at least 20% larger than Body Text  
 †Drug Facts Title to be larger than all other type used in DFP  
 ‡Box Barline may be omitted, and color contrast used to highlight Drug Facts Title



DRUG FACTS (NDC: 104050-0100)	RECORDED	ACTUAL ON FILE
Drug Name (NDC)	1/2/20	.
Drug Name (Generic)	7/8	.
Strength(s)	7/20/20/20	.
Drug Size	4/8	4/8
Tablets	3/8	3/8
Strength	1/2/20	1/2/20
Box and Bottle(s)	1/2/20/20	1/2/20/20

\* Strengths are in the order: Drug Name (NDC), Drug Name (Generic), Strength(s), Drug Size, Tablets, Strength, Box and Bottle(s).  
 \*\* Drug sizes are in the order: Drug Name (NDC), Drug Name (Generic), Strength(s), Drug Size, Tablets, Strength, Box and Bottle(s).  
 Drug sizes are in the order: Drug Name (NDC), Drug Name (Generic), Strength(s), Drug Size, Tablets, Strength, Box and Bottle(s).



FDA00194-3

DRUG FACTS INFO: (Modified Format - updated 5/19/11)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	7.1 pt
Drug Facts Continued	7 pt	7 pt
Headings*	7 pt-bold italic <sup>†</sup>	7 pt
Subheadings	≤6 pt	6 pt
Body Text	≤6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0 pt	0 - 0.25 pt
Headlines	0.5 pt rule	0.5 pt
Box and Barlines <sup>‡</sup>	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 30	≤30

\* Headings are to be at least 20% larger than Body Text.  
<sup>†</sup> Drug Facts Title to be larger than all other type size used in DFP.  
<sup>‡</sup> Box Barlines may be omitted and color contrast used to highlight Drug Facts info.



200%




100%

Do not use if the seal is broken or missing.

**See Carton For Full Information. Warnings: Allergy Alert:**  
 Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, difficulty breathing, swelling of the face, lips, tongue, or throat, or severe dizziness.

**Warnings:** If an allergic reaction occurs, stop use and seek medical help right away. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding in some people. The chance is higher if you: ● are age 60 or older ● have had stomach ulcers ● are taking blood thinners (anticoagulant) or ● take a blood thinner

**868105114**



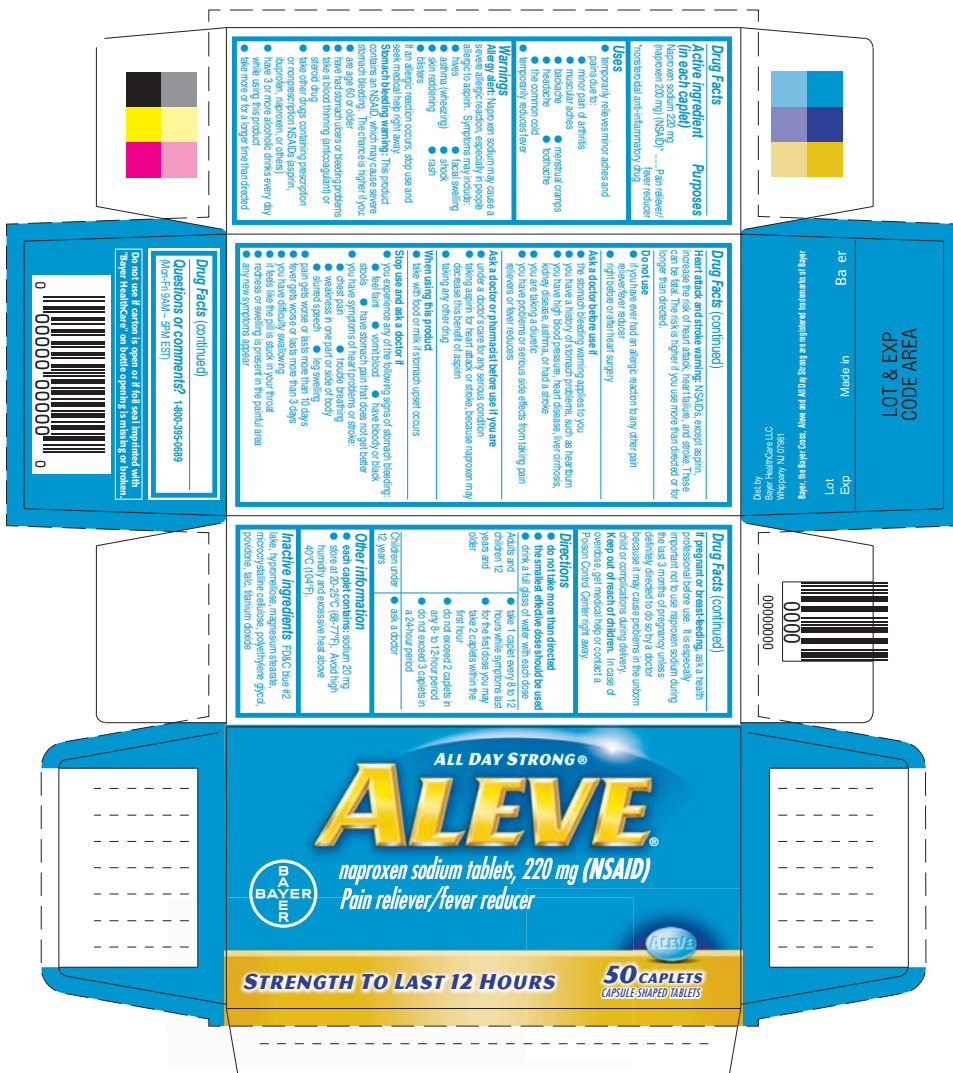
● take other drugs containing prescription or nonprescription NSAIDs, aspirin, ibuprofen, naproxen, or other NSAIDs. ● take more or for a longer time than directed. ● take more than 1 tablet at one time. ● use for longer than directed. ● use if you have ever had an allergic reaction to any other pain reliever/fever reducer. ● Ask a doctor or pharmacist before use if you are taking any other drug. ● Stop use if you experience any of the following signs of stomach bleeding: ● black or bloody or dark stools, have stomach pain that does not get better, have symptoms of heart problems (e.g. stroke, chest pain, shortness of breath, or fainting), or vomit, spit, or stool, slurred speech, loss of appetite, or other signs or symptoms. ● If pregnant or breast-feeding, ask a health professional before use. ● Keep out of reach of children. In case of overdose, call your doctor or poison control center or call 1-800-342-9773. For the first dose you may take 2 tablets with the first hour. Do not exceed 3 tablets in a 24-hour period. Children under 12 years of age should use only under the supervision of a doctor. ● Nuprin — SPV-ESD, Inc., Bayer HealthCare LLC, Whippany, NJ 07981

● take other drugs containing prescription or nonprescription NSAIDs, aspirin, ibuprofen, naproxen, or other NSAIDs. ● take more or for a longer time than directed. ● take more than 1 tablet at one time. ● use for longer than directed. ● use if you have ever had an allergic reaction to any other pain reliever/fever reducer. ● Ask a doctor or pharmacist before use if you are taking any other drug. ● Stop use if you experience any of the following signs of stomach bleeding: ● black or bloody or dark stools, have stomach pain that does not get better, have symptoms of heart problems (e.g. stroke, chest pain, shortness of breath, or fainting), or vomit, spit, or stool, slurred speech, loss of appetite, or other signs or symptoms. ● If pregnant or breast-feeding, ask a health professional before use. ● Keep out of reach of children. In case of overdose, call your doctor or poison control center or call 1-800-342-9773. For the first dose you may take 2 tablets with the first hour. Do not exceed 3 tablets in a 24-hour period. Children under 12 years of age should use only under the supervision of a doctor. ● Nuprin — SPV-ESD, Inc., Bayer HealthCare LLC, Whippany, NJ 07981

**ICL** Updated 2/27/19

CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	-
Drug Facts Continued	7 pt*	-
Headings	7 pt- <b>bold italic</b> <sup>a</sup>	-
Subheadings	6 pt*	4.5 pt
Body Text	6 pt*	4.5 pt
Bullets	5 pt	8 pt
Headlines	0.5 pt rule	-
Footlines <sup>†</sup>	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.  
<sup>a</sup>ICL minimum font size is 4.5 pt.  
<sup>\*</sup>< 0.5 pt leading may be used as long as ascenders and descenders do not touch.  
<sup>†</sup> FDA recommends size 2.5 pt type



FDA00200-1

DRUG FACTS INFO (updated 5/18/16)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. <sup>**</sup>	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	8 pt.-bold italic <sup>†</sup>	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0 pt. - 0.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 38	≤38

\* Headings are to be at least 20pt larger than Body Text.  
<sup>\*\*</sup> Drug Facts Title to be larger than all other type size used in DPP  
<sup>†</sup> FDA Recommendations 2-Sp Rule



200%




100%

Do not use if the seal is broken.

**See Carton For Full Information. Warnings: Allergy Alert:**  
 Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, difficulty breathing, swelling of the face, lips, tongue, or throat. Stop use and seek medical help right away. **Stomach Bleeding Warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: • are age 60 or older • have had stomach ulcers • take a blood thinner (anticoagulant) or

**868105114**



Do not use if the seal is broken.

• take other drugs containing prescription or nonprescription NSAIDs, aspirin, ibuprofen, naproxen, or other drugs that may increase the risk of bleeding when used with this product. • take more or for a longer time than directed. **Heart attack and stroke warning:** NSAIDs, when used for a long time, may increase the risk of heart attack, heart failure, or stroke. The risk is higher if you have heart disease, high blood pressure, or if you have ever had an allergic reaction to any other pain reliever/fever reducer. **Ask a doctor or pharmacist before use if you are taking any other drug. Stop use if you experience any of the following signs of stomach bleeding:** (See full prescribing information for details.)

- black or bloody stools
- vomit

Do not use if the seal is broken.


• take other drugs containing prescription or nonprescription NSAIDs, aspirin, ibuprofen, naproxen, or other drugs that may increase the risk of bleeding when used with this product. • take more or for a longer time than directed. **Heart attack and stroke warning:** NSAIDs, when used for a long time, may increase the risk of heart attack, heart failure, or stroke. The risk is higher if you have heart disease, high blood pressure, or if you have ever had an allergic reaction to any other pain reliever/fever reducer. **Ask a doctor or pharmacist before use if you are taking any other drug. Stop use if you experience any of the following signs of stomach bleeding:** (See full prescribing information for details.)

- black or bloody stools
- vomit

**ICL** Updated 2/27/19

CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt <sup>2</sup>	-
Drug Facts Continued	7 pt <sup>2</sup>	-
Headings	7 pt- <b>bold italic</b> <sup>3</sup>	-
Subheadings	6 pt <sup>2</sup>	4.5 pt
Body Text	6 pt <sup>2</sup>	4.5 pt
Bullets	5 pt	8 pt
Headlines	0.5 pt rule	-
Footlines <sup>1</sup>	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.  
<sup>1</sup>ICL minimum font size is 4.5 pt.  
<sup>2</sup>< 0.5 pt leading may be used as long as ascenders and descenders do not touch.  
<sup>3</sup> FDA recommends size 2.5 pt type



**ALEVE**  
naproxen sodium tablets, 220 mg (NSAID)  
Pain reliever/fever reducer

**100 CAPLETS**  
CAPSULE-SHAPED TABLETS

**Drug Facts**

**Warnings**

**Directions**

**Other information**

**Questions or comments?**

**Drug Facts (continued)**

**Directions**

**Other information**

**Questions or comments?**

**Drug Facts (continued)**

**Directions**

**Other information**

**Questions or comments?**

**Drug Facts (continued)**

**Directions**

**Other information**

**Questions or comments?**



FDA00190-1

DRUG FACTS INFO (Updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	1-8 pt. <sup>1*</sup>	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings <sup>2*</sup>	8 pt.-bold italic <sup>2*</sup>	8 pt.
Subheadings	1-8 pt.	8 pt.
Body Text	1-8 pt.	8 pt.
Bullets	5 pt.	12 pt.
Leading	>0.5 pt.	0.5 - 0.7 pt.
Headlines	0.5 pt rule	0.5 pt.
Box and Borderline	>0.5 pt rule	2.5 pt.
Characters Per Inch	No more than 28	1-28

<sup>1\*</sup> Headings are to be in bold. Size varies per block.  
<sup>2\*</sup> Drug Facts Title to be larger than all other type sizes used in DPP.  
<sup>3</sup> FDA Requirement 2.5pt rule

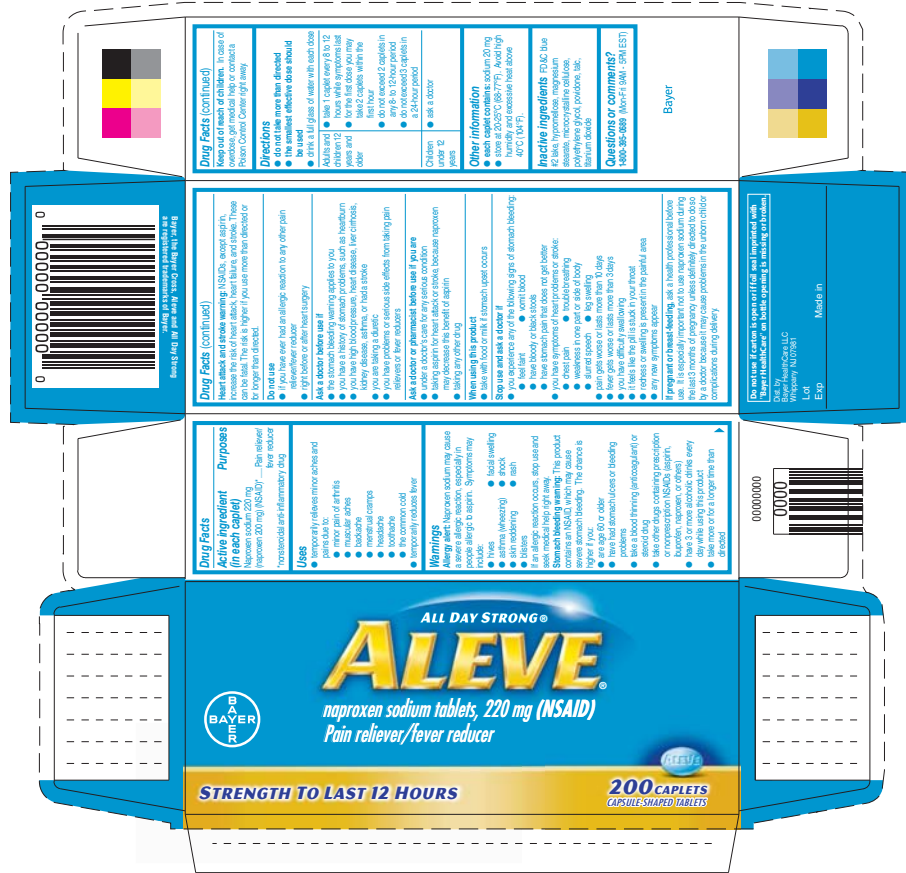


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FDA00197-1

DRUG FACTS INFO		
UPDATED	REQUIRED	ACTUAL IN FILE
Updated 5/18/13		
Drug Facts Title	>= 6 pt. <sup>**</sup>	6.1 pt.
Drug Facts Continued	6 pt.	6 pt.
Headings <sup>**</sup>	6 pt.-bold italic <sup>**</sup>	6 pt.
Subheadings	>= 6 pt.	6 pt.
Body text	>= 6 pt.	6 pt.
Bullets	5 pt.	1.2 pt.
Footnote	>= 6 pt.	6.0 pt.
Footnote	12 pt. min.	12.5 pt.
Box and Barcodes <sup>**</sup>	>= 6 pt. min.	2.5 pt.
Characters Per Inch	No more than 30	<= 30

<sup>\*</sup> Headings are to be at least 20px larger than Body Text.  
<sup>\*\*</sup> Drug Facts Title to be larger than all other type size used in DFP if DFP Requirements 2 Apply.



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**See Carton for Full Information**  
**Warnings Allergy alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin redness, rash, or blisters. If an allergic reaction occurs, stop use and seek medical help right away. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinning (anticoagulant) or steroid drug ● take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed. **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer or right before or after heart surgery. **Ask a doctor before use** if the stomach bleeding warning applies to you, you have a history of stomach problems (such as heartburn), you have high blood pressure, heart disease, liver cirrhosis, or kidney disease, asthma, or had a stroke, you are taking a diuretic, you have problems or serious side effects from taking pain relievers or fever reducers. **Ask a doctor or pharmacist before use** if you are under a doctor's care for any serious condition or taking any other drug. **When using this product** take with food or milk if stomach upset occurs. **Stop use and ask a doctor** if you experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, you have difficulty swallowing, it feels like the pill is stuck in your throat, redness or swelling is present in the genital area, or any new symptoms appear. **If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions Do not take more than directed. The smallest effective dose should be used.** Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 caplet every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 2 caplets in any 8- to 12-hour period. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). **Questions or comments? 1-800-395-9689 (Mon-Fri 9AM - 5PM EST)**



FDA00250-1

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	-
Drug Facts Continued	7 pt*	-
Headings	7 pt-bold italic*	4.5 pt
Subheadings	6 pt*	4.5 pt
Body Text	6 pt*	4.5 pt
Bullets	5 pt	8 pt
Hairlines	0.5 pt rule	-
Barlines†	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.  
 \* ICL minimum font size is 4.5 pt.  
 † 0.5 pt leading may be used as long as ascenders and descenders do not touch.  
 † FDA recommends size 2.5 pt type



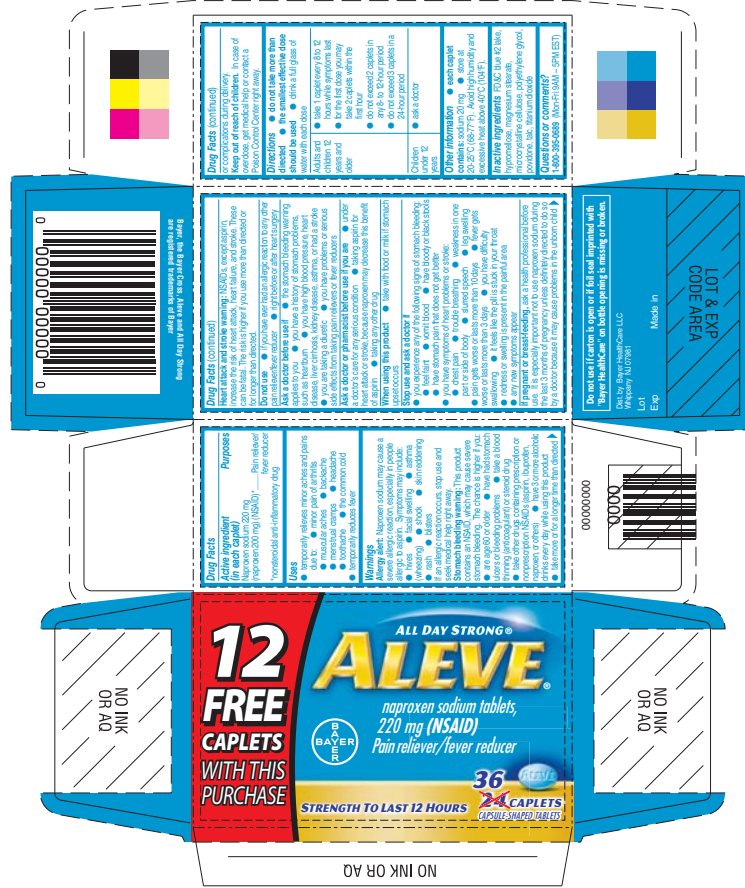


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FDA00199-1

DRUG FACTS INFO: Modified Format - updated 07/11		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	7.1 pt
Drug Facts Continued	7 pt	7 pt
Headings*	7 pt bold table†	7 pt
Sub-headings	≥5 pt	6 pt
Body Text	≥5 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥1 pt	0 - 0.5 pt
Headlines	0.5 pt rule	0.5 pt
Box and Barlines†	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 30	≤30

\* Headings are to be at least 20px larger than Body Text.  
† Drug Facts Title can be larger than all other text size used in a copy.  
‡ Box Barline may be omitted and color contrast used to highlight Drug Facts info.



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**Do not use if (do not use if you have):**

- Allergic reactions to aspirin or other salicylates, especially in patients allergic to aspirin. Symptoms may include hives, itching, or swelling of the face, lips, or tongue. Stop use and seek medical help right away. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance of stomach bleeding is greater when NSAIDs are used for longer periods of time, at higher doses, or in combination with other drugs that can increase the risk of bleeding problems.
- Have a bleeding problem (such as hemorrhoids, hemophilia, or a blood thinner (anticoagulant) or antiplatelet drug).

**See Caution for Full Information Warnings. Allergy alert.**

Aspirin (acetylsalicylic acid) is a salicylate. Salicylates may irritate the stomach and cause stomach pain. Stop use and seek medical help right away if you experience stomach pain that does not go away, especially if you have symptoms of heart problems or some other condition that may be affected by aspirin. Symptoms may include:

- Swelling of the face, lips, or tongue.
- Difficulty breathing.
- Dizziness or lightheadedness.
- Fainting.
- Stomach pain or heartburn.
- Coughing up blood or vomit that looks like coffee grounds.
- Black, tarry stools.
- Blood in the urine.
- Blood in the stool.
- A change in the color of your stool.



**Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer. Ask a doctor or pharmacist if you are unsure.**

**Stop use and ask a doctor if you experience any of the following signs of stomach bleeding (bleeding in the stomach):**

- Vomiting blood or material that looks like coffee grounds.
- Black, tarry stools.
- Blood in the urine.
- Blood in the stool.
- A change in the color of your stool.
- Stomach pain or heartburn.
- Coughing up blood or vomit that looks like coffee grounds.
- Difficulty breathing.
- Dizziness or lightheadedness.
- Fainting.
- Stomach pain or heartburn.
- Coughing up blood or vomit that looks like coffee grounds.
- Difficulty breathing.
- Dizziness or lightheadedness.
- Fainting.

**Use as directed. Do not take more than directed. Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack and stroke. The risk is greater with higher doses, longer treatment, or if you use more than directed or for longer than directed. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer. Ask a doctor or pharmacist if you are unsure.

**Use with caution:** Do not use if you are taking other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, celecoxib, rofecoxib, meloxicam, salsalate, etc.) or if you are taking other drugs that may increase the risk of stomach bleeding, such as aspirin, NSAIDs, or blood thinners (warfarin, etc.). Do not use if you are taking other drugs that may increase the risk of bleeding problems, such as aspirin, NSAIDs, or blood thinners (warfarin, etc.).

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center at 1-800-368-5643. For the first dose you may take 2 capsules within the first hour. Do not take more than 4 capsules in a 24-hour period. Do not take more than 12 capsules in a 30-day period. Do not take more than 3 capsules at one time.

**Warnings:**

- **Aspirin:** Adults and children 12 years and older. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer. Ask a doctor or pharmacist if you are unsure.
- **NSAID (EST):** Use by Bayer Healthcare LLC, Whippany, NJ 07981.

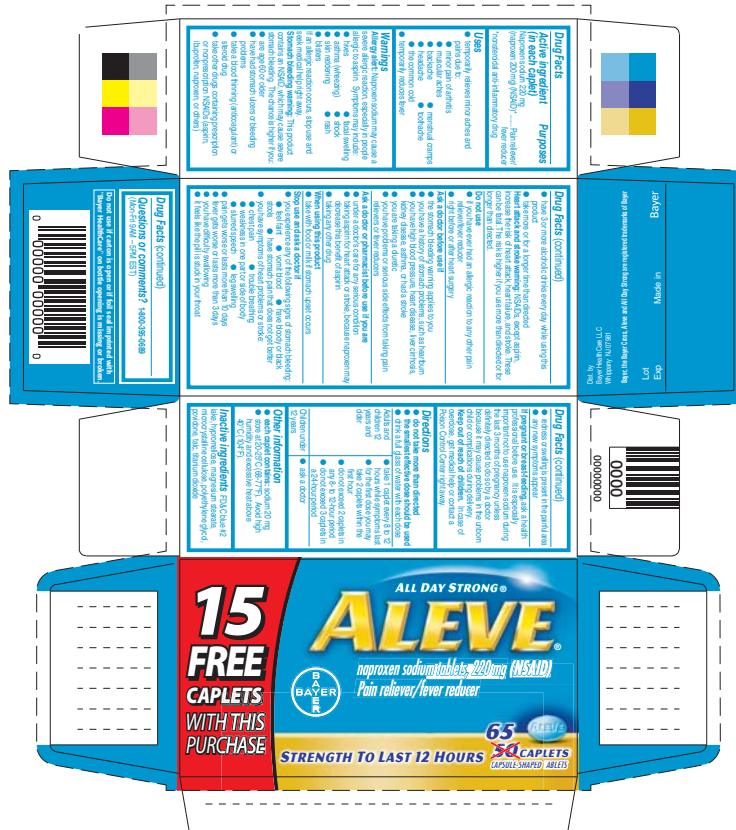
**Other information:**

- Contains aspirin.
- Contains NSAID (EST).
- Contains salicylates.
- Contains aspirin.
- Contains NSAID (EST).
- Contains salicylates.

**ICL (updated 2/27/19)**

CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	NA
Drug Facts Continued	7 pt*	NA
Headings	7 pt- <b>bold italic</b> *	4.5 pt
Subheadings	6 pt*	4.5 pt
Body Text	6 pt*	4.5 pt
Bullets	5 pt*	6 pt
Headlines	0.5 pt rule	NA
Baselines†	> 0.5 pt rule	NA

\*Character per inch rule is not applicable to ICL.  
 †ICL font sizes are 4.5 pt.  
 ‡ICL font sizes are 4.5 pt. ICL font sizes are 4.5 pt.  
 † FDA recommends size 2.5 pt type.



FDA00189-1

DRUG FACTS INFO (Updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>= 8 pt. <sup>1)</sup>	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings <sup>2)</sup>	8 pt. bold italic <sup>3)</sup>	8 pt.
Subheadings	>= 5 pt.	6 pt.
Body Text	>= 5 pt.	6 pt.
Bullets	5 pt.	12 pt.
Lineing	>= 0.5 pt.	0.5 pt. - 0.2 pt.
Horizontal	0.5 pt. rule	0.5 pt.
Box and Borderline	>= 0.5 pt. rule	2.0 pt.
Characters Per Inch	No more than 30	<= 30

<sup>1)</sup> Headings are 1.5 to 2.0 times larger than Body Text.  
<sup>2)</sup> Drug Facts Title is the largest size of all other sizes and used in GSP.  
<sup>3)</sup> FDA Recommends 8-Point



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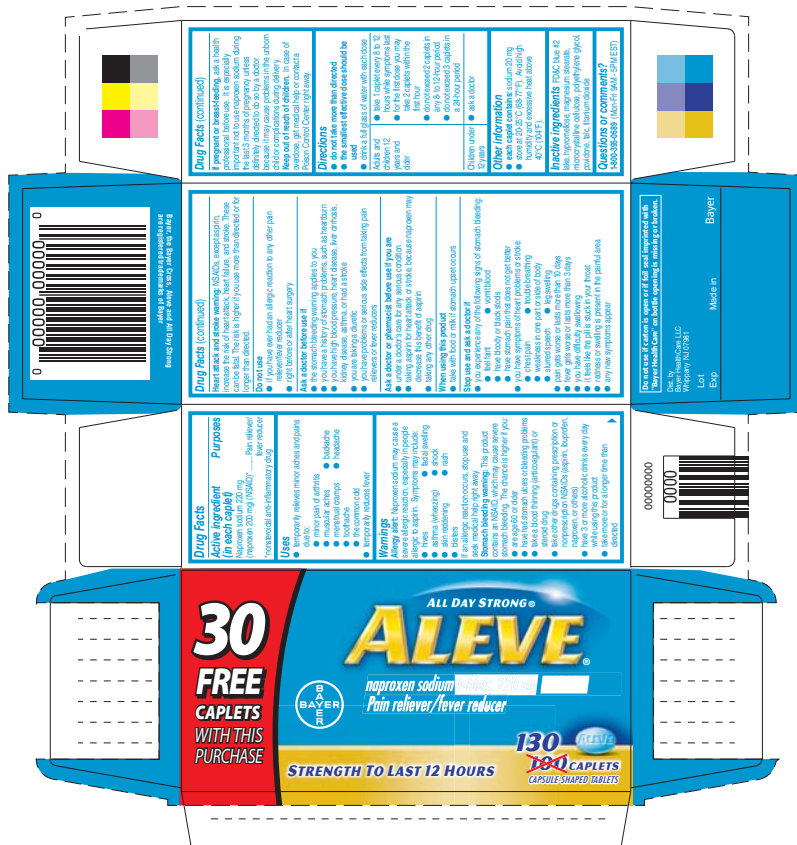
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**See Patient For Full Information**

**Warnings** Improves sodium intake. **Caution** Use with caution in patients with a history of asthma, allergies, or other respiratory conditions. **Contraindications** Do not use if you are pregnant or breastfeeding. **Side Effects** May cause dizziness, lightheadedness, or fainting. **Interactions** May interact with other medications. **Storage** Store at room temperature. **Expiration** Use before the expiration date. **Manufacturer** Bayer HealthCare LLC, Whippany, NJ 07981

DRUG FACTS INFO	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	-
Drug Facts Continued	8 pt.	-
Headings <sup>1</sup>	8 pt.-bold italic <sup>1</sup>	-
Subheadings	≥6 pt.	4.5 pt.
Body Text	≥6 pt.	4.5 pt.
Bullets	5 pt.	8 pt.
Leading	>0.5 pt.	4.5 pt.
Headlines	0.5 pt. rule	-
Box and Barlines <sup>1</sup>	>0.5 pt. rule	-
Characters Per Inch:	No more than 39	>39

<sup>1</sup> Headings are to be at least 6 pts. larger than Body Text.  
<sup>2</sup> Drug Facts Title to be larger than all other type size used in DFP.  
<sup>3</sup> FDA Recommends 6.3pt. rule



FDA00195-1

DRUG FACTS INFO (Updated 5/19/15)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>= 8 pt. <sup>1)</sup>	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Warnings <sup>2)</sup>	8 pt. bold italic <sup>3)</sup>	8 pt.
Schheadings	>= 8 pt.	8 pt.
Body Text	>= 8 pt.	8 pt.
Bullets	5 pt.	12 pt.
Leading	>= 5 pt.	0.5 pt.
Headlines	0.5 pt rule	0.5 pt.
Box and Barlines <sup>4)</sup>	>= 5 pt rule	2.5 pt.
Characters Per Inch	No more than 28	<= 28

<sup>1)</sup> Warnings are in 8 pt. bold, 28pt. larger than Body Text.  
<sup>2)</sup> Drug Facts Title to be larger than all other text, not used in DTP.  
<sup>3)</sup> FDA Recommendations & Specifications.



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**See Carton For Full Information Warnings Allergy alert:**  
Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin redness, rash, or blisters. If an allergic reaction occurs, stop use and seek medical help right away. **Stomach**

**Medding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinning (anticoagulant) or steroid drug ● take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed. **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer or right before or after heart surgery. **Ask a doctor before use** if the stomach bleeding warning applies to you, you have a history of stomach problems (such as heartburn), you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke, you are taking a diuretic, you have problems or serious side effects from taking pain relievers or fever reducers. **Ask a doctor or pharmacist before use** if you are under a doctor's care for any serious condition or taking any other drug. **When using this product** take with food or milk; if stomach upset occurs, **Stop use and ask a doctor** if you experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, you have difficulty swallowing, it feels like the pill is stuck in your throat, redness or swelling is present in the painful area, or any new symptoms appear. **If pregnant or breast-feeding,** ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions:** Adults and children 12 years and older: take 1 caplet with water every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor. **Questions or comments? 1-800-395-0689** (Mon-Fri 9AM - 5PM EST)

85704583 | Doc. by: Boyer HealthCare LLC  
Whippany, NJ 07981

DRUG FACTS INFO: (Modified Format – updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	-
Drug Facts Continued	7 pt	-
Headings*	7 pt-bold italic*	-
Subheadings	≥6 pt	4.5 pt
Body Text	≥6 pt	4.5 pt
Bullets	5 pt	8 pt
Leading	≥0 pt	4.75 pt
Hairlines	0.5 pt rule	-
Box and Barlines†	>0.5 pt rule	-
Characters Per Inch:	No more than 39	≥ 39

\* Headings are to be at least 2pts larger than Body Text  
\*\* Drug Facts Title to be larger than all other type size used in DFP  
† Box Barline may be omitted and color contrast used to highlight Drug Facts Info





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**See Carton For Full Information Warnings Allergy alert:**

Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, or blisters. If an allergic reaction occurs, stop use and seek medical help right away. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinning (anticoagulant) or steroid drug ● take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed. **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer or right before or after heart surgery. **Ask a doctor before use** if the stomach bleeding warning applies to you, you have a history of stomach problems (such as heartburn), you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke, you are taking a diuretic, you have problems or serious side effects from taking pain relievers or fever reducers. **Ask a doctor or pharmacist before use if you are under a doctor's care** for any serious condition or taking any other drug. **When using this product** take with food or milk if stomach upset occurs. **Stop use and ask a doctor if you** experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, you have difficulty swallowing, it feels like the pill is stuck in your throat, redness or swelling is present in the painful area, or any new symptoms appear. **If pregnant or breast-feeding**, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions** Adults and children 12 years and older: take 1 caplet with water every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor. **Questions or comments? 1-800-395-0689** (Mon-Fri 9AM - 5PM EST)


 Dist. by: Bayer HealthCare LLC  
Whippany, NJ 07981

**See Carton For Full Information Warnings Allergy alert:**

Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, or blisters. If an allergic reaction occurs, stop use and seek medical help right away. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinning (anticoagulant) or steroid drug ● take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed. **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer or right before or after heart surgery. **Ask a doctor before use** if the stomach bleeding warning applies to you, you have a history of stomach problems (such as heartburn), you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke, you are taking a diuretic, you have problems or serious side effects from taking pain relievers or fever reducers. **Ask a doctor or pharmacist before use if you are under a doctor's care** for any serious condition or taking any other drug. **When using this product** take with food or milk if stomach upset occurs. **Stop use and ask a doctor if you** experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, you have difficulty swallowing, it feels like the pill is stuck in your throat, redness or swelling is present in the painful area, or any new symptoms appear. **If pregnant or breast-feeding**, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions** Adults and children 12 years and older: take 1 caplet with water every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor. **Questions or comments? 1-800-395-0689** (Mon-Fri 9AM - 5PM EST)


 Dist. by: Bayer HealthCare LLC  
Whippany, NJ 07981

DRUG FACTS INFO (continued 5/12/19)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	-
Drug Facts Continued	8 pt.	-
Headings†	8 pt.-bold italic†	-
Subheadings	≥6 pt.	4.5 pt.
Body text	≥6 pt.	4.5 pt.
Bullets	5 pt.	8 pt.
Listing	≥0.5 pt.	25 pt.
Headlines	≥0.5 pt rule	-
Box and Barlines†	≥0.5 pt rule	-
Characters Per Inch	Not more than 35	> 39

†† Headings are to be at least 20pt larger than Body text.  
\*\* Drug Facts Title to be larger than all other type size used in DFP  
†††A Recommendations 2.5pt rule



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**25 FREE CAPLETS WITH THIS PURCHASE**

**ALL DAY STRONG®**

# ALEVE®

naproxen sodium tablets, 220 mg

Pain reliever/fever reducer

**225 280 CAPLETS**

**STRENGTH TO LAST 12 HOURS**

**280 CAPSULE-SHAPED TABLETS**

00000000



**Drug Facts (continued)**

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- take with food or milk
- the smallest effective dose should be used

**Warnings**

- do not take if you have had stomach ulcers or bleeding in the stomach or intestines
- do not take if you are taking aspirin, salicylates, or other NSAIDs
- do not take if you are taking blood thinners
- do not take if you are taking other NSAIDs
- do not take if you are taking other pain relievers
- do not take if you are taking other drugs that may increase the risk of stomach ulcers or bleeding
- do not take if you are taking other drugs that may increase the risk of kidney problems
- do not take if you are taking other drugs that may increase the risk of heart problems
- do not take if you are taking other drugs that may increase the risk of liver problems
- do not take if you are taking other drugs that may increase the risk of low blood pressure
- do not take if you are taking other drugs that may increase the risk of dizziness or lightheadedness
- do not take if you are taking other drugs that may increase the risk of blurred vision
- do not take if you are taking other drugs that may increase the risk of ringing in the ears
- do not take if you are taking other drugs that may increase the risk of skin rash
- do not take if you are taking other drugs that may increase the risk of allergic reactions
- do not take if you are taking other drugs that may increase the risk of severe allergic reactions
- do not take if you are taking other drugs that may increase the risk of anaphylaxis
- do not take if you are taking other drugs that may increase the risk of asthma
- do not take if you are taking other drugs that may increase the risk of hives
- do not take if you are taking other drugs that may increase the risk of swelling
- do not take if you are taking other drugs that may increase the risk of difficulty breathing
- do not take if you are taking other drugs that may increase the risk of wheezing
- do not take if you are taking other drugs that may increase the risk of chest pain
- do not take if you are taking other drugs that may increase the risk of trouble breathing
- do not take if you are taking other drugs that may increase the risk of heart problems or stroke
- do not take if you are taking other drugs that may increase the risk of pain gets worse or lasts more than 10 days
- do not take if you are taking other drugs that may increase the risk of fever gets worse or lasts more than 3 days
- do not take if you are taking other drugs that may increase the risk of you have already swollen
- do not take if you are taking other drugs that may increase the risk of you have a fever
- do not take if you are taking other drugs that may increase the risk of redness or swelling is present in the genital area
- do not take if you are taking other drugs that may increase the risk of any new symptoms appear

**Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
- taking any other drug
- taking any other drug

**When using this product**

- take with food or milk if stomach upset occurs
- stop use and ask a doctor if
- you experience any of the following signs of stomach bleeding:
  - black, tarry stools
  - vomit blood
  - blood in urine
  - dark, bloody stools
- you have stomach pain that does not go away
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness or dizziness
  - slurred speech
  - loss of consciousness
  - sudden weakness or numbness
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have already swollen
- you have a fever
- redness or swelling is present in the genital area
- any new symptoms appear

**If pregnant or breast-feeding, ask a health professional before use.** It is especially important to use naproxen sodium during the last 3 months of pregnancy unless a health professional directs you to do so. Use during pregnancy may cause problems in the unborn child or complications during delivery.

**Drug Facts (continued)**

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- take with food or milk
- the smallest effective dose should be used

**Warnings**

- do not take if you have had stomach ulcers or bleeding in the stomach or intestines
- do not take if you are taking aspirin, salicylates, or other NSAIDs
- do not take if you are taking blood thinners
- do not take if you are taking other NSAIDs
- do not take if you are taking other pain relievers
- do not take if you are taking other drugs that may increase the risk of stomach ulcers or bleeding
- do not take if you are taking other drugs that may increase the risk of kidney problems
- do not take if you are taking other drugs that may increase the risk of heart problems
- do not take if you are taking other drugs that may increase the risk of liver problems
- do not take if you are taking other drugs that may increase the risk of low blood pressure
- do not take if you are taking other drugs that may increase the risk of dizziness or lightheadedness
- do not take if you are taking other drugs that may increase the risk of blurred vision
- do not take if you are taking other drugs that may increase the risk of ringing in the ears
- do not take if you are taking other drugs that may increase the risk of skin rash
- do not take if you are taking other drugs that may increase the risk of allergic reactions
- do not take if you are taking other drugs that may increase the risk of severe allergic reactions
- do not take if you are taking other drugs that may increase the risk of anaphylaxis
- do not take if you are taking other drugs that may increase the risk of asthma
- do not take if you are taking other drugs that may increase the risk of hives
- do not take if you are taking other drugs that may increase the risk of swelling
- do not take if you are taking other drugs that may increase the risk of difficulty breathing
- do not take if you are taking other drugs that may increase the risk of wheezing
- do not take if you are taking other drugs that may increase the risk of chest pain
- do not take if you are taking other drugs that may increase the risk of trouble breathing
- do not take if you are taking other drugs that may increase the risk of heart problems or stroke
- do not take if you are taking other drugs that may increase the risk of pain gets worse or lasts more than 10 days
- do not take if you are taking other drugs that may increase the risk of fever gets worse or lasts more than 3 days
- do not take if you are taking other drugs that may increase the risk of you have already swollen
- do not take if you are taking other drugs that may increase the risk of you have a fever
- do not take if you are taking other drugs that may increase the risk of redness or swelling is present in the genital area
- do not take if you are taking other drugs that may increase the risk of any new symptoms appear

**Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
- taking any other drug
- taking any other drug

**When using this product**

- take with food or milk if stomach upset occurs
- stop use and ask a doctor if
- you experience any of the following signs of stomach bleeding:
  - black, tarry stools
  - vomit blood
  - blood in urine
  - dark, bloody stools
- you have stomach pain that does not go away
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness or dizziness
  - slurred speech
  - loss of consciousness
  - sudden weakness or numbness
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have already swollen
- you have a fever
- redness or swelling is present in the genital area
- any new symptoms appear

**If pregnant or breast-feeding, ask a health professional before use.** It is especially important to use naproxen sodium during the last 3 months of pregnancy unless a health professional directs you to do so. Use during pregnancy may cause problems in the unborn child or complications during delivery.

**Drug Facts (continued)**

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- take with food or milk
- the smallest effective dose should be used

**Warnings**

- do not take if you have had stomach ulcers or bleeding in the stomach or intestines
- do not take if you are taking aspirin, salicylates, or other NSAIDs
- do not take if you are taking blood thinners
- do not take if you are taking other NSAIDs
- do not take if you are taking other pain relievers
- do not take if you are taking other drugs that may increase the risk of stomach ulcers or bleeding
- do not take if you are taking other drugs that may increase the risk of kidney problems
- do not take if you are taking other drugs that may increase the risk of heart problems
- do not take if you are taking other drugs that may increase the risk of liver problems
- do not take if you are taking other drugs that may increase the risk of low blood pressure
- do not take if you are taking other drugs that may increase the risk of dizziness or lightheadedness
- do not take if you are taking other drugs that may increase the risk of blurred vision
- do not take if you are taking other drugs that may increase the risk of ringing in the ears
- do not take if you are taking other drugs that may increase the risk of skin rash
- do not take if you are taking other drugs that may increase the risk of allergic reactions
- do not take if you are taking other drugs that may increase the risk of severe allergic reactions
- do not take if you are taking other drugs that may increase the risk of anaphylaxis
- do not take if you are taking other drugs that may increase the risk of asthma
- do not take if you are taking other drugs that may increase the risk of hives
- do not take if you are taking other drugs that may increase the risk of swelling
- do not take if you are taking other drugs that may increase the risk of difficulty breathing
- do not take if you are taking other drugs that may increase the risk of wheezing
- do not take if you are taking other drugs that may increase the risk of chest pain
- do not take if you are taking other drugs that may increase the risk of trouble breathing
- do not take if you are taking other drugs that may increase the risk of heart problems or stroke
- do not take if you are taking other drugs that may increase the risk of pain gets worse or lasts more than 10 days
- do not take if you are taking other drugs that may increase the risk of fever gets worse or lasts more than 3 days
- do not take if you are taking other drugs that may increase the risk of you have already swollen
- do not take if you are taking other drugs that may increase the risk of you have a fever
- do not take if you are taking other drugs that may increase the risk of redness or swelling is present in the genital area
- do not take if you are taking other drugs that may increase the risk of any new symptoms appear

**Ask a doctor or pharmacist before use if you are**


- under a doctor's care for any serious condition
- taking any other drug
- taking any other drug

**When using this product**

- take with food or milk if stomach upset occurs
- stop use and ask a doctor if
- you experience any of the following signs of stomach bleeding:
  - black, tarry stools
  - vomit blood
  - blood in urine
  - dark, bloody stools
- you have stomach pain that does not go away
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness or dizziness
  - slurred speech
  - loss of consciousness
  - sudden weakness or numbness
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have already swollen
- you have a fever
- redness or swelling is present in the genital area
- any new symptoms appear

**If pregnant or breast-feeding, ask a health professional before use.** It is especially important to use naproxen sodium during the last 3 months of pregnancy unless a health professional directs you to do so. Use during pregnancy may cause problems in the unborn child or complications during delivery.

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Do not use if **Caution** is open or if **Seal** is missing or broken.

Bayer HealthCare LLC  
Whippany, NJ 07981

Lot  
Exp

Made in

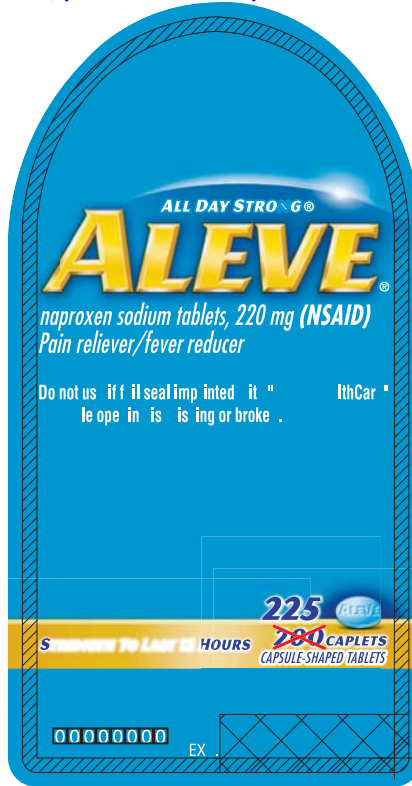
**LOT & EXP CODE AREA**

PS



DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>=8 pt **	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings†	8 pt-bold/italic†	8 pt
Subheadings	>=6 pt	6 pt
Body Text	>=6 pt	6 pt
Bullets	5 pt	12 pt
Leading	>0.5 pt	0.8 pt
Hairlines	0.5 pt rule	0.5 pt
Box and Barlines†	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 35	>39

† Headings are to be at least 20pt larger than Body Text.  
\*\* Drug Facts Title to be larger than all other type size used in DPP  
† FDA Recommends 2.5pt rule



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**See Carton for Full Information**  
**Warnings Allergy alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin redness, rash, or blisters. If an allergic reaction occurs, stop use and seek medical help right away. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinning (anticoagulant) or steroid drug ● take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed. **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer or right before or after heart surgery. **Ask a doctor before use** if the stomach bleeding warning applies to you, you have a history of stomach problems (such as heartburn), you have high blood pressure, heart disease, liver cirrhosis, or kidney disease, asthma, or had a stroke, you are taking a diuretic, you have problems or serious side effects from taking pain relievers or fever reducers. **Ask a doctor or pharmacist before use** if you are under a doctor's care for any serious condition or taking any other drug. **When using this product** take with food or milk if stomach upset occurs. **Stop use and ask a doctor** if you experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, you have difficulty swallowing, it feels like the pill is stuck in your throat, redness or swelling is present in the painful area, or any new symptoms appear. **If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions Do not take more than directed. The smallest effective dose should be used.** Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 caplet every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 2 caplets in any 8- to 12-hour period. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). **Questions or comments? 1-800-395-9689 (Mon-Fri 9AM - 5PM EST)**

Dist. by:  
 Bayer HealthCare LLC  
 Whippany, NJ 07981



FDA00250-1

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	-
Drug Facts Continued	7 pt*	-
Headings	7 pt-bold italic*	4.5 pt
Subheadings	6 pt*	4.5 pt
Body Text	6 pt*	4.5 pt
Bullets	5 pt	8 pt
Hairlines	0.5 pt rule	-
Barlines†	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.  
 \* ICL minimum font size is 4.5 pt.  
 † 0.5 pt leading may be used as long as ascenders and descenders do not touch.  
 † FDA recommends size 2.5 pt type

**Drug Facts (continued)**

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

**Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

**When using this product**

- take with food or milk if stomach upset occurs

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat

**Drug Facts (continued)**

- redness or swelling is present in the painful area
- any new symptoms appear

**If pregnant or breast-feeding, ask a health professional before use.** It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

**Adults and children 12 years and older**

- take 1 caplet every 8 to 12 hours while symptoms last
- on the first dose you may take 2 caplets within the first hour
- do not exceed 2 caplets in any 8- to 12-hour period
- do not exceed 3 caplets in a 24-hour period

**Children under 12 years**

- ask a doctor

**Other information**

- each caplet contains sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

**Inactive ingredients** FDAC blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

**Questions or comments?** 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

LOT & EXP. AREA

Made in [ ]

LOT [ ]

**SOFT GRIP® ARTHRITIS CAP**

**ALL DAY STRONG®**

**ALEVE®**

Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

**SOFT GRIP® ARTHRITIS CAP**

**ALL DAY STRONG®**

**ALEVE®**

naproxen sodium tablets, 220 mg (NSAID)  
Pain reliever/fever reducer

THIS PACKAGE IS CHILD-RESISTANT

**STRENGTH TO LAST 12 HOURS**

**50 CAPLETS**  
CAPSULE-SHAPED TABLETS

Dist. by Bayer HealthCare LLC, Whippany, NJ 07981  
Bayer the Bayer Cross, Aleve, All Day Strong and Soft Grip are registered trademarks of Bayer

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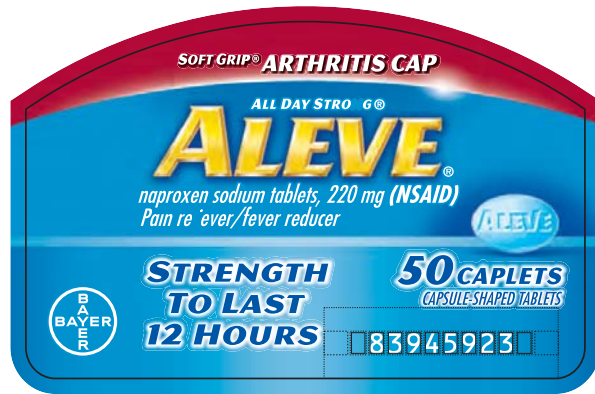
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PS

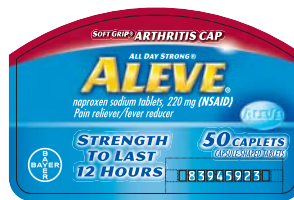
FDA00172-1

DRUG FACTS INFO Updated 5/19/18		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	8.1 pt.
Drug Facts Continued	8 pt.	9 pt.
Headings†	8 pt.-bold italic†	9 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 pt.
Headlines	0.5 pt. min.	0.5 pt.
Box and Borderline	≥0.5 pt. min.	2.5 pt.
Characters Per Inch	No more than 39	≥39

† Headings are to be at least 20% larger than Body Text.  
\*\* Drug Facts Title to be larger than all other type size used in DFP.  
† FDA recommends 2.5pt. min.



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Keep out of reach of children. In case of overdose, call your healthcare provider for advice about the next steps to take. If you have any questions about this medicine, ask your healthcare provider. Call or check the FDA website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). © 2015, Bayer Healthcare LLC. All rights reserved.

Keep out of reach of children. In case of overdose, call your healthcare provider for advice about the next steps to take. If you have any questions about this medicine, ask your healthcare provider. Call or check the FDA website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). © 2015, Bayer Healthcare LLC. All rights reserved.

Keep out of reach of children. In case of overdose, call your healthcare provider for advice about the next steps to take. If you have any questions about this medicine, ask your healthcare provider. Call or check the FDA website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). © 2015, Bayer Healthcare LLC. All rights reserved.

Keep out of reach of children. In case of overdose, call your healthcare provider for advice about the next steps to take. If you have any questions about this medicine, ask your healthcare provider. Call or check the FDA website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). © 2015, Bayer Healthcare LLC. All rights reserved.

DRUG FACTS INFO updated 5/19/18	RECORDED	ACTUAL IN FILE
Category		
Drug Facts Title	1.8.14	
Drug Facts Content	1.8.14	
Manufactured by	Bayer HealthCare LLC	
Strength	1.8.14	1.8.14
Box Type	1.8.14	1.8.14
Boxes	1.8.14	1.8.14
Location	1.8.14	1.8.14
Barcode	1.8.14	1.8.14
Barcode Per Inch	1.8.14	1.8.14
Character Per Inch	1.8.14	1.8.14

\*Headings are for information only. All data is for informational purposes only. © 2015, Bayer Healthcare LLC. All rights reserved.

**Drug Facts (continued)**

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

**Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

**When using this product**

- take with food or milk if stomach upset occurs

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
  - pain gets worse or lasts more than 10 days
  - fever gets worse or lasts more than 3 days
  - you have difficulty swallowing
  - it feels like the pill is stuck in your throat
  - redness or swelling is present in the painful area
  - any new symptoms appear

**Drug Facts (continued)**

**If pregnant or breast-feeding, ask a health professional before use.** It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

**Adults and children 12 years and older**

- take 1 caplet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 caplets within the first hour
- do not exceed 2 caplets in any 8- to 12-hour period
- do not exceed 3 caplets in a 24-hour period

**Children under 12 years**

- ask a doctor

**Other information**

- each caplet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

**Inactive ingredients** FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

**Questions or comments?** 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

Bayer

Exp. Lot  
Made in

SOFT GRIP® ARTHRITIS CAP  
ALL DAY STRONG®  
**ALEVE**®

SOFT GRIP® ARTHRITIS CAP  
ALL DAY STRONG®  
**ALEVE**®  
naproxen sodium tablets, 220 mg (NSAID)  
Pain reliever/fever reducer



THIS PACKAGE IS CHILD-RESISTANT


**STRENGTH TO LAST 12 HOURS**  
**150 CAPLETS**  
 CAPSULE-SHAPED TABLETS

Do not use this product if oriented safety seal bearing "Bayer HealthCare" under cap is torn or missing.  
 Bayer, the Bayer Cross, Aleve, All Day Strong and Soft Grip are registered trademarks of Bayer.



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**Drug Facts**

Active ingredient (in each caplet)	Purposes
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)	Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug

**Uses**

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscular aches
  - backache
  - menstrual cramps
  - headache
  - toothache
  - the common cold
  - temporarily reduces fever

**Warnings**

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- ulcers

If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.



FDA0198-1

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt**	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings†	8 pt bold italic	8 pt
Subheadings	>6 pt	6 pt
Body Text	>6 pt	6 pt
Bullets	5 pt	12 pt
Leading	>0.5 pt	1 - 1.5 pt
Horlines	0.5 pt rule	0.5 pt
Box and Barlines‡	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 39	<39

† Headings are to be at least 20% larger than Body Text.  
 \*\* Drug Facts Text to be larger than all other type size used in ODP.  
 ‡ FDA Recommends 2.5pt rule.



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FDA00178-2

CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	1.0 pt	0.1 pt
Drug Facts Content	0.1 pt	0.1 pt
Warnings*	1.0 pt and subpart	0.1 pt
Subheadings	1.0 pt	0.1 pt
Body Text	1.0 pt	0.1 pt
Tables	0.1 pt	0.1 pt
Linking	0.5 pt	1.0 pt
Headlines	0.5 pt rule	0.5 pt
Box and Barcodes†	0.5 pt rule	0.5 pt
Chemistry Panel	Requires Step 3	0.0

\*Headlines are up to the last Step larger than Step Text.  
†Box rules include the weight than all other type rules used in DDP.  
†FDA Requirement 2.56.06



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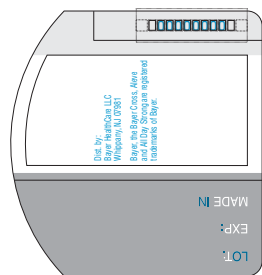
100%

**Drug Facts**  
 Active ingredient (in each caplet) Purpose  
 Naproxen sodium 220 mg (NSAID)<sup>1</sup> Pain reliever/fever reducer  
 Folic acid 1 mg Folic acid

**Directions**  
 Do not take more than directed.  
 Do not take more than directed.  
 Do not take more than directed.

**Other Information**  
 Contains 12 caplets in a 24-hour pack.  
 Children ask a doctor.

**Questions or comments?** 1-800-395-0889  
 (M-F, 9 AM - 5 PM EST)  
 Bayer



**Drug Facts (continued)**

**Warnings**  
 Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:  
 • hives (swelling)

**Directions**  
 Do not take more than directed. Do not take more than directed. Do not take more than directed.

**DRUG FACTS INFO** (based on 5 caplets)

CATEGORY	REQUIRE	ACTUAL IN FILE
Drug Facts Title	5/1 pt	5/1 pt
Drug Facts Content	5/1 pt	5/1 pt
Headings	5/1 pt	5/1 pt
Subheadings	5/1 pt	5/1 pt
Body Text	5/1 pt	5/1 pt
Summary	5/1 pt	5/1 pt
Other	5/1 pt	5/1 pt
Drug Facts (Printed)	5/1 pt	5/1 pt
Drug Facts (Electronic)	5/1 pt	5/1 pt
Drug Facts (Mobile)	5/1 pt	5/1 pt
Drug Facts (Social Media)	5/1 pt	5/1 pt
Drug Facts (Audio/Video)	5/1 pt	5/1 pt
Drug Facts (Interactive)	5/1 pt	5/1 pt
Drug Facts (Other)	5/1 pt	5/1 pt
Drug Facts (Total)	5/1 pt	5/1 pt

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Do not use this product if printed under cap is torn or missing.

**OPEN TO READ DRUG FACTS BEFORE USE**

**LIFT HERE**



**Drug Facts**

Active ingredient (in each caplet):  
Naproxen sodium  
250 mg  
Ibuprofen  
200 mg  
Pain reliever  
(NSAID)<sup>1</sup>  
Naproxen sodium  
250 mg  
Pain reliever  
(NSAID)<sup>2</sup>

**Drug Facts** (continued)

Prepares or reconstitutes, use a health professional before use. It is especially important to use naproxen sodium with ibuprofen because they may cause problems in the unborn child or complications during delivery.

**Directions**

- Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
- Do not take more than directed.
- Do not take more than directed.
- Do not take more than directed.

**Warnings**

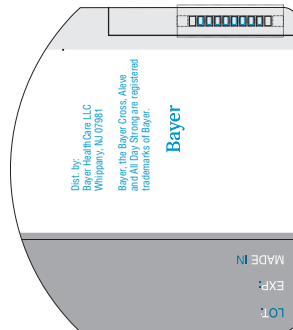
- Do not take more than directed.
- Do not take more than directed.
- Do not take more than directed.

**Other information**

- Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
- Do not take more than directed.
- Do not take more than directed.

**Questions or comments? 1-800-988-0889**

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**Drug Facts** (continued)

**Warnings**

- Do not use if you have had an allergic reaction to any other pain reliever.
- Do not use if you have had an allergic reaction to any other pain reliever.
- Do not use if you have had an allergic reaction to any other pain reliever.

**Uses**

- Temporarily relieves minor aches and pains due to:
- Headaches
- Muscle aches
- Arthritis
- Dental pain
- Menstrual cramps
- Joint pain
- Backache
- Neurachic
- Common cold
- Phenylalanine

**Directions**

- Take 1 caplet every 8 to 12 hours.
- Do not take more than directed.
- Do not take more than directed.

**Other information**

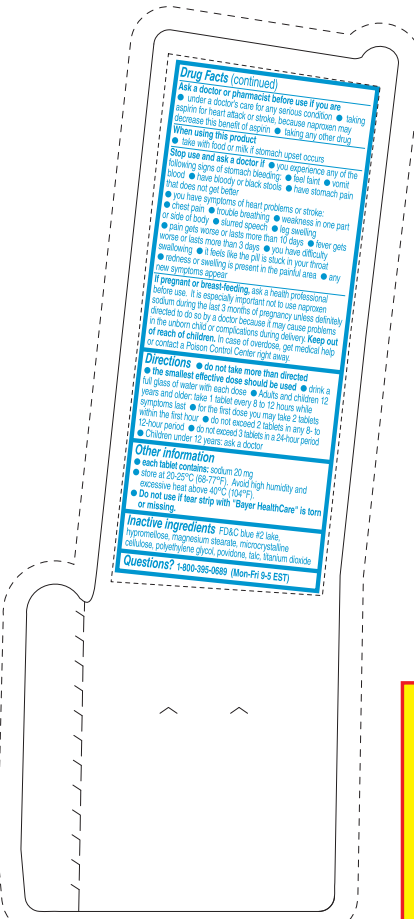
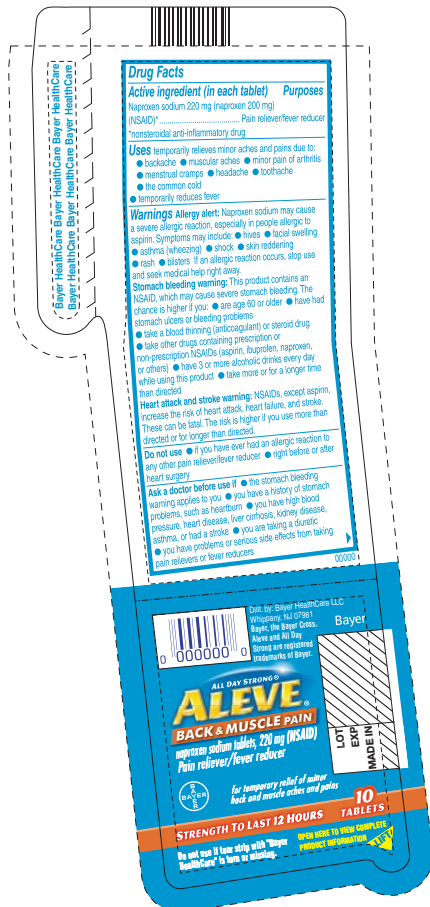
- Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
- Do not take more than directed.
- Do not take more than directed.

**Questions or comments? 1-800-988-0889**

**FDAC01033-1**

CATEGORY	REQUIRED	ACTUAL	UNIT
Direct Care Use	56.0%	8.1%	0.1%
Over-the-Counter	8.0%	5.0%	0.1%
Healthcare	8.0%	5.0%	0.1%
Salmonella	5.0%	5.0%	0.1%
Both Use	5.0%	5.0%	0.1%
Blades	5.0%	5.0%	0.1%
Washing	5.0%	5.0%	0.1%
Showering	5.0%	5.0%	0.1%
Over-the-Counter	5.0%	5.0%	0.1%
Direct Care Use	5.0%	5.0%	0.1%

\* Includes a table 4 used by Bayer HealthCare.   
† Includes a table 4 used by Bayer HealthCare.   
‡ Includes a table 4 used by Bayer HealthCare.



**Drug Facts**

**Active ingredient (in each tablet)** Naproxen sodium 220 mg (naproxen 200 mg) (NSAID) Pain reliever/fever reducer

**Purposes** temporarily relieves minor aches and pains due to:

- backache
- muscular aches
- minor pain of arthritis
- menstrual cramps
- headache
- toothache
- the common cold

temporarily reduces fever

**Warnings** Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, dizziness. If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older, have had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others), have 3 or more alcoholic drinks every day while using this product, take more or for a longer time than directed.

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer, right before or after heart surgery.

**Ask a doctor before use** if: the stomach bleeding warning applies to you, you have a history of stomach problems, such as heartburn, you have high blood pressure, heart disease, liver problems, kidney disease, asthma, or had a stroke, you are taking a diuretic, or you have problems or serious side effects from taking pain relievers or fever reducers.

**Drug Facts (continued)**

**Ask a doctor or pharmacist before use if you are** under a doctor's care for any serious condition, taking aspirin for heart attack or stroke, because naproxen may increase the benefit of aspirin, taking any other drug, or taking any other drug.

**When using this product** take with food or milk, if stomach upset occurs.

**Stop use and ask a doctor if:** you experience any of the following signs of stomach bleeding: have bloody or black stools, feel faint, vomit that does not get better, you have symptoms of heart problems or stroke: chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling, pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, you have difficulty swallowing, it feels like the pill is stuck in your throat, redness or swelling is present in the painful area, or any new symptoms appear.

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use naproxen during the last 3 months of pregnancy unless directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions** do not take more than directed, the smallest effective dose should be used. Drink a full glass of water with each dose. Adults and children 12 years and older take 1 tablet every 8 to 12 hours while symptoms last. Do not exceed 2 tablets in any 8 to 12-hour period. Do not exceed 3 tablets in a 24-hour period. Children under 12 years: ask a doctor.

**Other information** each tablet contains: sodium 20 mg. Store at 20°C to 25°C (68°F to 77°F). Avoid high humidity and excessive heat above 40°C (104°F). Do not use if tear strip with "Bayer HealthCare" is torn or missing.

**Inactive ingredients** FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide.

**Questions?** 1-800-995-0689 (Mon-Fri 9-5 EST)

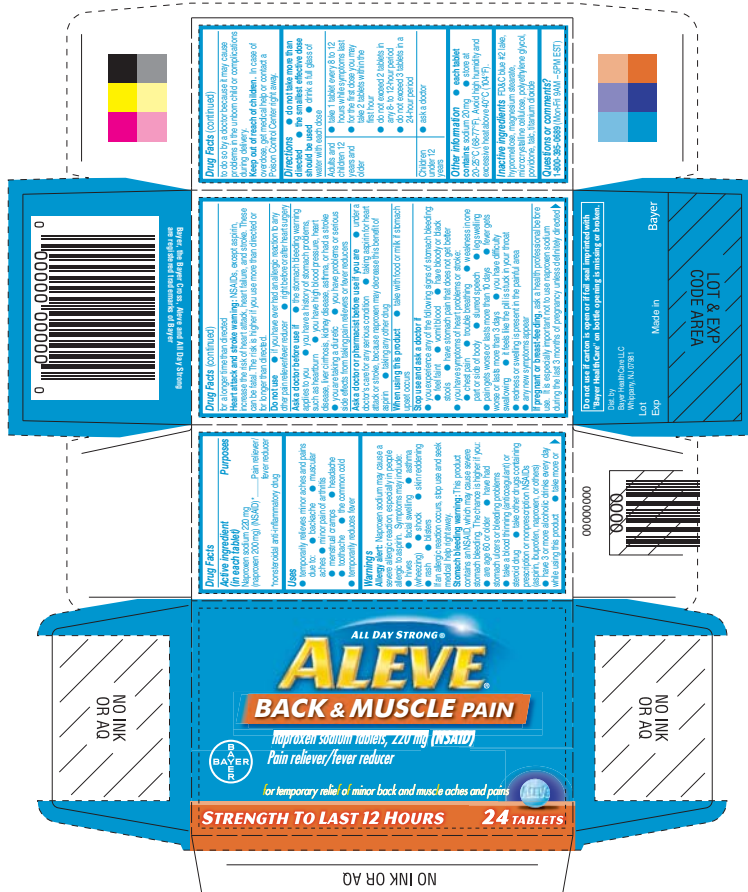
Actual Size 100%

FDA 00228-4

DRUG FACTS INFO	REMOVED	ACTUAL IN FDC
Drug Facts Box	28 pt.	9 pt.
Drug Facts Content	8 pt.	8 pt.
Warnings	395-500 text	8 pt.
Directions	28 pt.	8 pt.
Other Info	28 pt.	8 pt.
Other Ingredients	28 pt.	8 pt.
Other Information	28 pt.	8 pt.
Questions	28 pt.	8 pt.
Character Description	28 pt.	8 pt.
Character Description	28 pt.	8 pt.

\*Weighted average size based on the weight of the drug facts box.

†Drug Facts Box is the average size of all drug facts boxes used in FDC 00228-4.



FDA00248-1

DRUG FACTS INFO: Modified Format - updated 05/11/11		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	7.1 pt
Drug Facts Continued	7 pt	7.1 pt
Headings <sup>†</sup>	7 pt bold italic <sup>‡</sup>	7 pt
Sub-headings	8.5 pt	6 pt
Body Text	8.5 pt	6 pt
Bullets	5 pt	12 pt
Leading	3.0 pt	0 - 0.5 pt
Headlines	0.5 pt rule	0.5 pt
Box and Barlines <sup>§</sup>	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 30	≤30

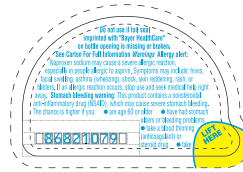
<sup>†</sup> Headings are to be at least 20% larger than Body Text.  
<sup>‡</sup> Drug Facts Title to be larger than all other text and use a 20%  
<sup>§</sup> Box Barline may be omitted and color contrast used to highlight Drug Facts title.



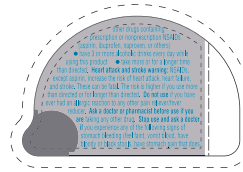
200%



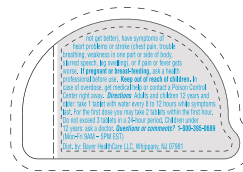
100%



Panel 1 Top



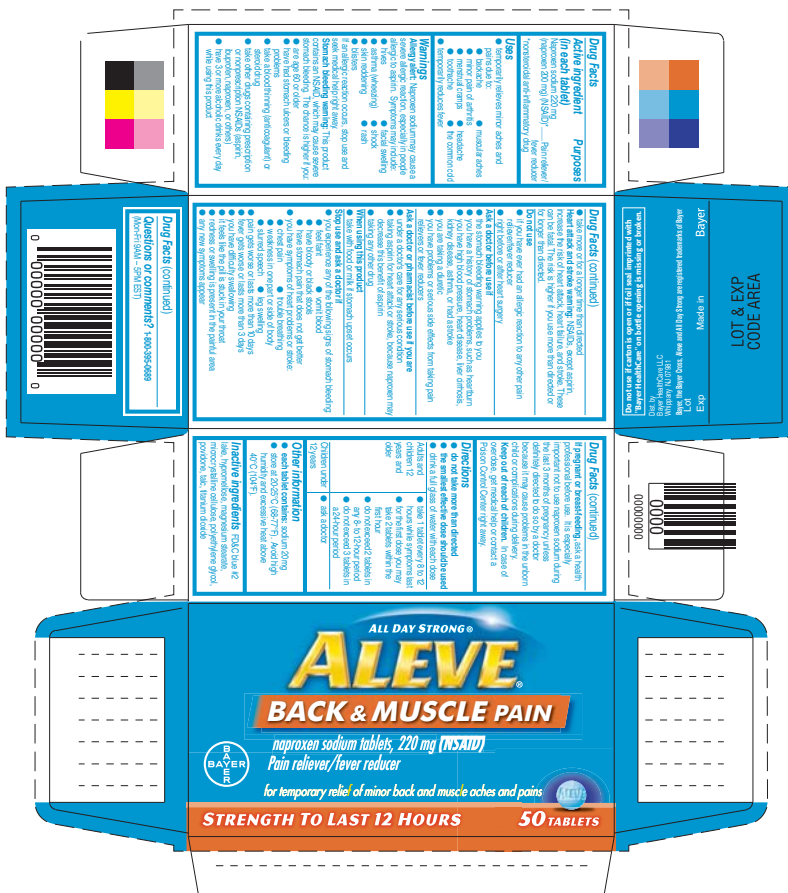
Panel 2 Inside



Panel 3 Base

ICL Formatted 2/27/18		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt	-
Drug Facts Continued	7 pt	-
Headings	7 pt-bold italic	4.5 pt
Subheadings	6 pt	4.5 pt
Body Text	6 pt	4.5 pt
Bullets	5 pt	8 pt
Footnotes	0.5 pt	-
Smallprint	> 0.5 pt	-

Characters per inch rule is not applicable to ICL.  
 ICL minimum font size is 4.5 pt.  
 - 0.5 pt heading may be used as long as ascenders and descenders do not touch.  
 1 FDA recommends size 2.5 pt type



FDA00202-1

DRUG FACTS INFO <small>Updated 5/19/19</small>		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>= 8 pt. **	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings <sup>†</sup>	8 pt.-bold italic <sup>†</sup>	8 pt.
Subheadings	>= 6 pt.	6 pt.
Body Text	>= 6 pt.	6 pt.
Bullets	6 pt.	12 pt.
Lead-in	>= 0.5 pt.	0. - 0.5 pt.
Header	0.5 pt.-rule	0.5 pt.
Box and Border	>= 0.5 pt.-rule	0.5 pt.
Characters Per Inch	No more than 35	35 <sup>†</sup>

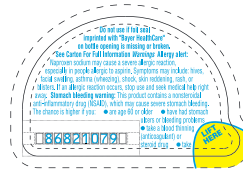
<sup>†</sup> Headings are to be at least 20pt larger than Body Text.  
<sup>\*\*</sup> Drug Facts Title to be larger than all other type size used in DRP if FDA Recommendations 2-8pt size.



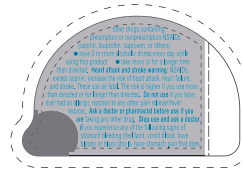
200%



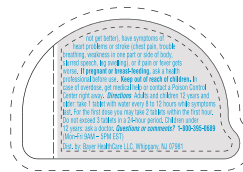
100%



Panel 1 Top



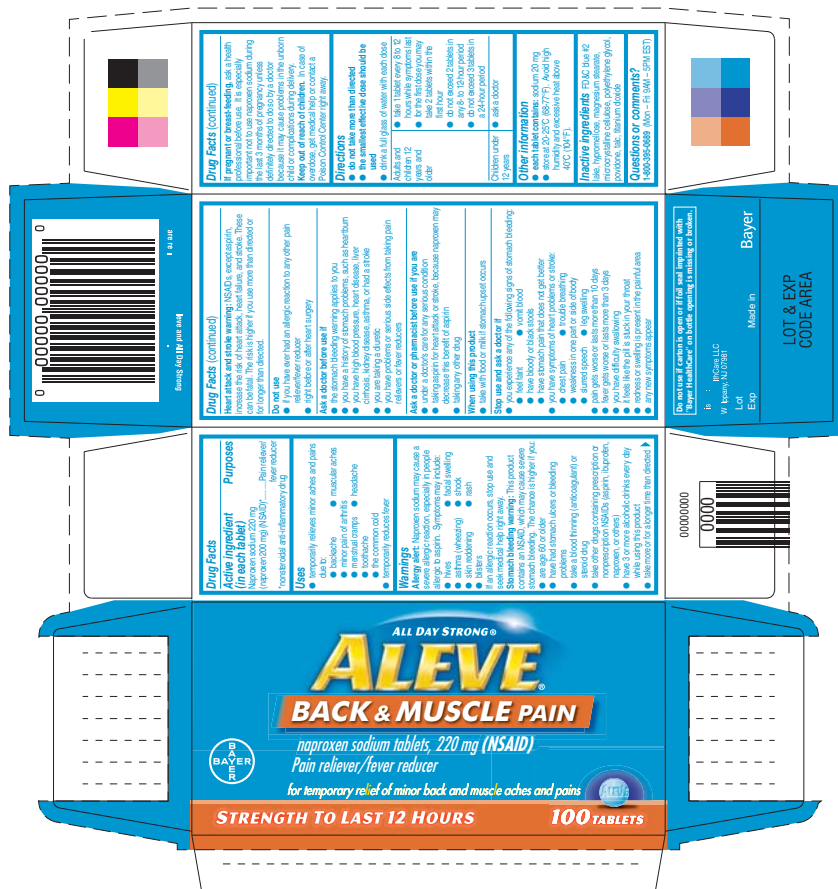
Panel 2 Inside



Panel 3 Base

ICL Formated 2/27/18		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt	-
Drug Facts Continued	7 pt	-
Headings	7 pt-bold italic	4.5 pt
Subheadings	6 pt	4.5 pt
Body Text	6 pt	4.5 pt
Bulleted	5 pt	8 pt
Footnote	0.5 pt	-
Smallprint	> 0.5 pt	-

Characters per inch rule is not applicable to ICL.  
 ICL minimum font size is 4.5 pt.  
 - 0.5 pt heading may be used as long as ascenders and descenders do not touch.  
 1 FDA recommends size 2.5 pt type



FD0A0203-2

DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings	8 pt bold italic <sup>†</sup>	8 pt
Subheadings	>6 pt	6 pt
Body Text	>6 pt	6 pt
Bullets	5 pt	12 pt
Leading	>0.5 pt	0.5 - 0.6 pt
Horizontal	0.5 pt rule	0.5 pt
Box and Barlines	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 38	<38

<sup>†</sup> Headings are to be at least 20% larger than Body Text.  
<sup>\*\*</sup> Drug Facts Title is larger than all other type size used in DDP.  
 † FDA Recommendations 2.5 pt rule.



200%



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See Carton for Full Information Warnings

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction which may include hives, facial swelling, asthma (wheezing) or shock. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: • are age 60 or older • have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or steroid drug • take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) • have 3 or more alcoholic drinks every day while using this product • take more or for a longer time than directed.

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer. **Stop use and ask a doctor** if you experience any of the following signs of stomach bleeding: (red, brown, or black stools, bloody or black stools, have stomach pain that does not get better), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), or if pain or fever gets worse. **If pregnant or breast-feeding,** ask a health professional before use. **Directions:** Adults and children 12 years and older: take 1 tablet with water every 8 to 12 hours while symptoms last. For the first dose you may take 2 tablets within the first hour. Do not exceed 3 tablets in a 24-hour period. Children under 12 years: ask a doctor. **Questions or comments?** 1-800-955-6689 (Mon-Fri 8AM - 5PM EST)

1857179521  
(Dist. by: Bayer HealthCare LLC  
Whispery, NJ 07981)

100%

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	-
Drug Facts Continued	8 pt	-
Headings <sup>†</sup>	8 pt bold italic <sup>†</sup>	-
Subheadings	≥6 pt	4.5 pt
Body Text	≥6 pt	4.5 pt
Bullets	5 pt	8 pt
Leading	≥0.5 pt	0 pt
Hairlines	0.5 pt rule	-
Box and Barlines <sup>†</sup>	>0.5 pt rule	-
Characters Per Inch:	No more than 39	≥39

<sup>†</sup> Headings are to be at least 2pts larger than Body Text.  
<sup>\*\*</sup> Drug Facts Title to be larger than all other type size used in DFP  
<sup>†</sup> FDA Recommends 2.5pt rule

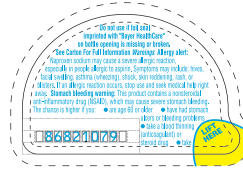


FDA00216-1

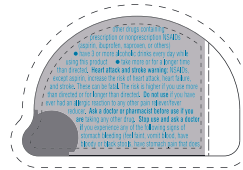
DRUG FACTS INFO: Original Form - Updated 5/18/11		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	≥ 7 pt	7.1 pt
Drug Facts Continued	7 pt	7 pt
Warnings*	7 pt bold italic	7 pt
Side effects	≥ 8 pt	8 pt
Black Box	≥ 8 pt	8 pt
Bullets	5 pt	12 pt
Contraindications	≥ 8 pt	8 pt
Directions	≥ 8 pt	8.5 pt
Use and Dosage	≥ 8.5 pt	8.5 pt
Chemicals Per Inch	No more than 30	30

\*Warnings are to be at least 20% larger than Black Box text.  
 \*\*Drug Facts Title is larger than all other text and is 20% larger than the smallest text in the entire file.  
 †The Bottom may be omitted and color contrast used to highlight drug facts info.

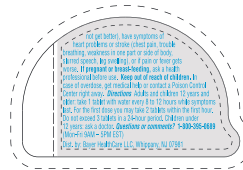




Panel 1 Top



Panel 2 Inside



Panel 3 Base

ICL Formatted 2/27/18	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt	-
Drug Facts Continued	7 pt	-
Headings	7 pt bold italic	4.5 pt
Subheadings	6 pt	4.5 pt
Body Text	6 pt	4.5 pt
Bullets	5 pt	8 pt
Footnote	0.5 pt	-
Smallprint	> 0.5 pt	-

Characters per inch rule is not applicable to ICL.  
 ICL minimum font size is 4.5 pt.  
 - 0.5 pt heading may be used as long as ascenders and descenders do not touch.  
 1 FDA recommends size 2.5 pt type

**Drug Facts**

**Active ingredient** (In each tablet)

**Purpose**

**Warnings**

**Directions**

**Other information**

**LOT & EXP CODE AREA**

Bayer  
 Made in  
 Exp

00000000

00000000

**Drug Facts (continued)**

**Questions or comments?**

**Drug Facts (continued)**

**Questions or comments?**

**Drug Facts (continued)**

**Questions or comments?**



FDA00218-1

DRUG FACTS INFO (Updated 5/18/10)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. <sup>1*</sup>	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings <sup>2†</sup>	8 pt. bold italic <sup>2</sup>	8 pt.
Subheadings	>6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	>0.5 pt.	0 - 0.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines <sup>2</sup>	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 30	<30

\* Headings are to be at least 20pt. larger than Body Text.  
<sup>††</sup> Drug Facts Title to be larger than all other type size used in DPP.  
<sup>†††</sup> FDA Recommendation: 2 Spc. rule



200%



100%



100%

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	-
Drug Facts Continued	8 pt	-
Headings <sup>†</sup>	8 pt bold italic <sup>†</sup>	-
Subheadings	≥6 pt	4.5 pt
Body Text	≥6 pt	4.5 pt
Bullets	5 pt	8 pt
Leading	≥0.5 pt	0 pt
Hairlines	0.5 pt rule	-
Box and Barlines <sup>†</sup>	>0.5 pt rule	-
Characters Per Inch:	No more than 39	≥39

<sup>†</sup> Headings are to be at least 2pts larger than Body Text.  
<sup>\*\*</sup> Drug Facts Title to be larger than all other type size used in DFP  
<sup>†</sup> FDA Recommends 2.5pt rule

**30 FREE TABLETS WITH THIS PURCHASE**

**ALL DAY STRONG® ALEVE®**

**BACK & MUSCLE PAIN**

*naproxen sodium tablets, 220 mg (NSAID)*

**Pain reliever/fever reducer**

*for temporary relief of minor back and muscle aches and pains*

**STRENGTH TO LAST 12 HOUR**

**130 TABLETS**

**Drug Facts (continued)**

**Directions**

- Take 1 tablet every 12 hours with food.
- Do not exceed 2 tablets in 24 hours.
- Do not exceed 3 tablets in 48 hours.
- Ask your doctor if you are taking other pain relievers, such as aspirin.

**Other information**

Keep out of reach of children. Use only as directed.

**Questions or comments?**

Call 1-800-4-A-LEVE (4253-8383) for more information.

**Drug Facts (continued)**

**Directions**

- Take 1 tablet every 12 hours with food.
- Do not exceed 2 tablets in 24 hours.
- Do not exceed 3 tablets in 48 hours.
- Ask your doctor if you are taking other pain relievers, such as aspirin.

**Other information**

Keep out of reach of children. Use only as directed.

**Questions or comments?**

Call 1-800-4-A-LEVE (4253-8383) for more information.

**Drug Facts (continued)**

**Directions**

- Take 1 tablet every 12 hours with food.
- Do not exceed 2 tablets in 24 hours.
- Do not exceed 3 tablets in 48 hours.
- Ask your doctor if you are taking other pain relievers, such as aspirin.

**Other information**

Keep out of reach of children. Use only as directed.

**Questions or comments?**

Call 1-800-4-A-LEVE (4253-8383) for more information.

Reference ID: 4597159



FDA00219-2

DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	≤85 pt**	81 pt
Drug Facts Continued	9 pt	9 pt
Headings†	8 pt bold 846††	8 pt
Subheadings†	≥45 pt	5 pt
Block Text	≥5 pt	8 pt
Bullets	5 pt	12 pt
Leading	≥3.5 pt	0.5 - 0.9 pt
Headlines	0.5 pt rule	0.5 pt
Block and Section	≥2.5 pt rule	2.5 pt
Characterize Font Size	Has more than 10	≤8

\* Headings are to be at least 20pt larger than Block Text.  
\*\* Drug Facts Title to be larger than other open size used in DPP in 12pt increments in 10pt rule.



200%



100%

See Carton  
for Full Information

**Warnings Allergy alert:** Naproxen sodium may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing) or shock. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinning (anticoagulant) or steroid drug ● take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed. **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use if** you have ever had an allergic reaction to any other pain reliever/fever reducer. **Stop use and ask a doctor** if you experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), or if pain or fever gets worse. **If pregnant or breast-feeding**, ask a health professional before use. **Directions** Adults and children 12 years and older: take 1 tablet with water every 8 to 12 hours while symptoms last. For the first dose you may take 2 tablets within the first hour. Do not exceed 3 tablets in a 24-hour period. Children under 12 years: ask a doctor. **Questions or comments? 1-800-395-0689** (Mon-Fri 9AM – 5PM EST)

Dist. by:  
Bayer HealthCare LLC  
Whippany, NJ 07981

**86601648**

DRUG FACTS INFO: (Modified Format – updated 5/18/16)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	-
Drug Facts Continued	7 pt	-
Headings <sup>a</sup>	7 pt- <b>bold italic</b> <sup>a</sup>	5 pt
Subheadings	≥6 pt	5 pt
Body Text	≥6 pt	5 pt
Bullets	5 pt	9 pt
Leading	≥0 pt	5.65 pt
Hairlines	0.5 pt rule	-
Box and Barlines <sup>f</sup>	>0.5 pt rule	-
Characters Per Inch:	No more than 39	> 39

<sup>a</sup> Headings are to be at least 2pts larger than Body Text.  
<sup>a</sup> Drug Facts Title to be larger than all other type size used in DPP  
<sup>f</sup> Box Barline may be omitted and color contrast used to highlight Drug Facts Info

**50 FREE TABLETS WITH THIS PURCHASE**

**ALL DAY STRONG® ALEVE®**  
naproxen sodium tablets, 220 mg (NSAID)  
Pain reliever/fever reducer

**STRENGTH TO LAST 12 HOURS** 150 TABLETS

**Drug Facts (continued)**

If pregnant or becoming pregnant, ask a health care professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless instructed to do so because of the risk of serious or fatal complications during delivery. Keep out of reach of children. In case of overdose, call your healthcare provider or Poison Control Center right away.

**Directions**

- take 1 tablet every 8 to 12 hours with water.
- do not take more than directed.
- take 2 tablets with the first hour.
- do not exceed 3 tablets in any 8- to 12-hour period.
- do not exceed 3 tablets in a 24-hour period.

Children under 12 years

**Other information**

- each tablet contains sodium 20 mg.
- keep out of reach of children.
- keep in original container to protect from light, humidity, and excessive heat above 47°C (104°F).

**Inactive ingredients** FMC Blue 42 like, hydroxyethyl cellulose, polyethylene glycol, microcrystalline cellulose, polyethylene glycol, croscarmellose sodium, titanium dioxide.

**Questions or comments?**  
1-800-338-0888 (Mon–Fri 9AM–5PM EST)

**Drug Facts (continued)**

Most stomach and digestive warning NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These risks can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever of this type.
- right before or after heart surgery.

**Ask a doctor before use if**

- the stomach bleeding warning applies to you.
- you have a history of stomach problems, such as heartburn or indigestion.
- you have high blood pressure, heart disease, liver disease, kidney disease, asthma, or had a stroke.
- you are taking a diuretic.
- you have problems or serious side effects from taking pain relievers or fever reducers.

**Ask a doctor or pharmacist before use if you use**

- under a doctor's care for any chronic condition, such as heart disease, kidney disease, or asthma.
- decrease the benefit of aspirin.
- taking any other drug.

**When using this product**

- take with food or milk if stomach upset occurs.
- you experience any of the following signs of stomach bleeding:
  - black or bloody stools.
  - have stomach pain that does not get better after taking antacids.
  - have symptoms of heart problems or stroke:
    - chest pain
    - trouble breathing
    - shortness of breath
    - slurred speech
    - leg swelling
  - pain gets worse or lasts more than 10 days
  - fever gets worse or lasts more than 3 days
  - if feels like the pill is stuck in your throat
  - redness or swelling is present in the painful area
  - any new symptoms appear

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
  - black or bloody stools.
  - have stomach pain that does not get better after taking antacids.
  - have symptoms of heart problems or stroke:
    - chest pain
    - trouble breathing
    - shortness of breath
    - slurred speech
    - leg swelling
  - pain gets worse or lasts more than 10 days
  - fever gets worse or lasts more than 3 days
  - if feels like the pill is stuck in your throat
  - redness or swelling is present in the painful area
  - any new symptoms appear

**Drug Facts (continued)**

**Active ingredient** (each tablet)  
Naproxen sodium 220 mg (NSAID)  
naproxen sodium (NSAID), Pain reliever/fever reducer

**Purposes**  
• temporarily relieves minor aches and pains such as:

- headache
- muscle aches
- minor pain of arthritis
- menstrual cramps
- flu-like symptoms
- toothaches
- the common cold

temporarily reduces fever.

**Uses**  
temporarily relieves minor aches and pains such as:

- headache
- muscle aches
- minor pain of arthritis
- menstrual cramps
- flu-like symptoms
- toothaches
- the common cold

temporarily reduces fever.

**Warnings**

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms of a severe allergic reaction include:

- hives
- rash
- difficulty breathing
- swollen face
- throat
- hoarseness
- wheezing
- skin redness
- itching
- dizziness
- fainting
- loss of consciousness

stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach ulcers, bleeding, or perforation without warning. The risk is higher if you are age 60 or older, have had stomach ulcers or bleeding problems, take other drugs containing prescription or over-the-counter NSAIDs (aspirin, ibuprofen, naproxen, etc.), take other drugs containing prescription or over-the-counter NSAIDs (aspirin, ibuprofen, naproxen, etc.), or drink alcohol while using this product.

- have 3 or more alcoholic drinks every day while using this product.
- take more for a longer time than directed.

**Drug Facts (continued)**

**Directions**

- take 1 tablet every 8 to 12 hours with water.
- do not take more than directed.
- take 2 tablets with the first hour.
- do not exceed 3 tablets in any 8- to 12-hour period.
- do not exceed 3 tablets in a 24-hour period.

Children under 12 years

**Other information**

- each tablet contains sodium 20 mg.
- keep out of reach of children.
- keep in original container to protect from light, humidity, and excessive heat above 47°C (104°F).

**Inactive ingredients** FMC Blue 42 like, hydroxyethyl cellulose, polyethylene glycol, microcrystalline cellulose, polyethylene glycol, croscarmellose sodium, titanium dioxide.

**Questions or comments?**  
1-800-338-0888 (Mon–Fri 9AM–5PM EST)

0 000000 000000

**Barcode**

00000000

**Barcode**



FDA00220-2

DRUG FACTS INFO (updated 5/19/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>6 pt. <sup>**</sup>	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings <sup>†</sup>	8 pt.-bold italic <sup>†</sup>	8 pt.
Subheadings	>6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	>0.5 pt.	0.5 pt.
Horizontals	0.5 pt. rule	0.5 pt.
Box and Barlines <sup>†</sup>	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 39	<39

<sup>\*\*</sup> Headings are to be at least 200% larger than Body Text.  
<sup>†</sup> Drug Facts Title to be larger than all other type size used in DPP if FDA Recommends 2.5pt. rule.



200%



100%

See Carton  
for Full Information

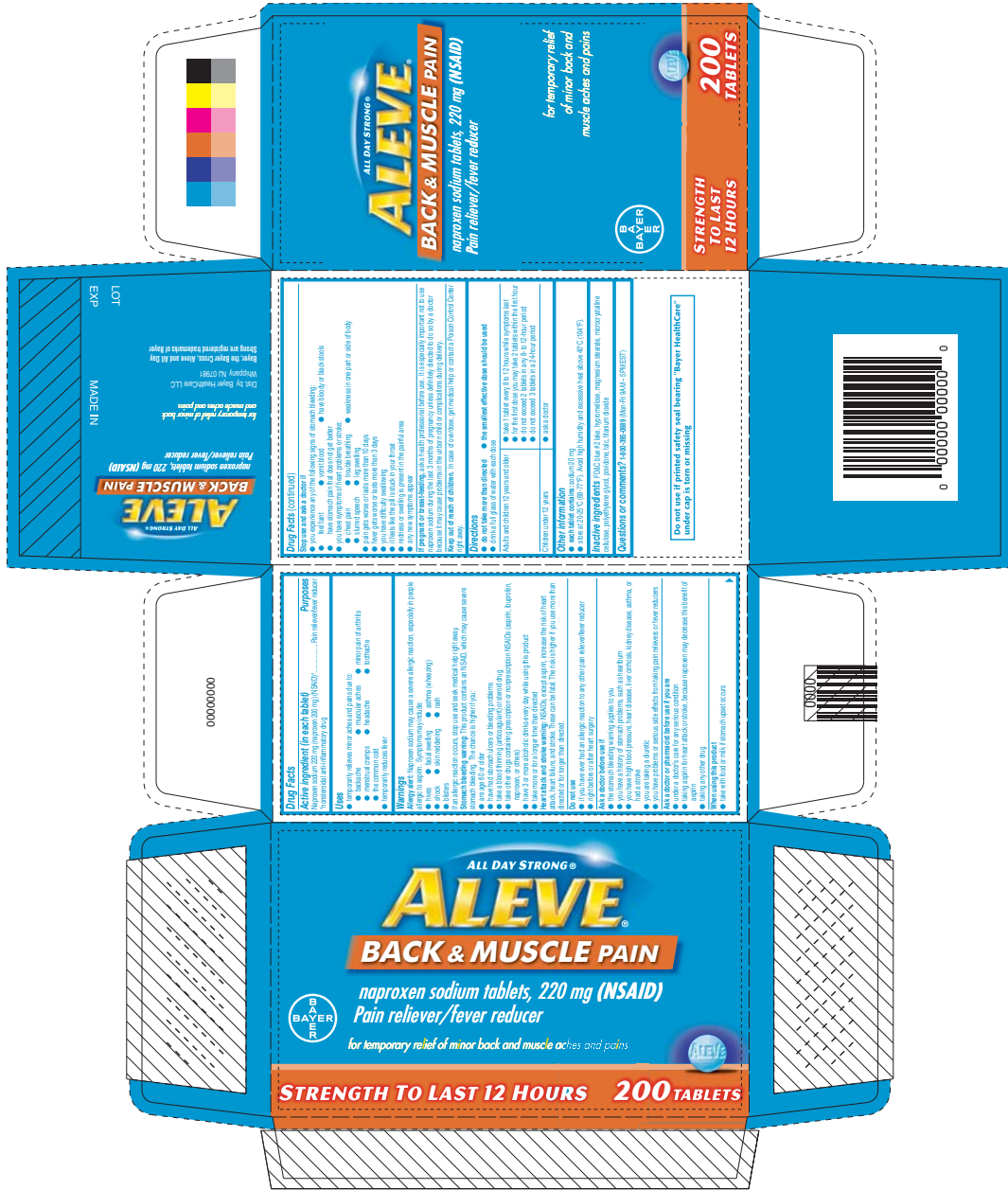
**Warnings Allergy alert:** Naproxen sodium may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing) or shock. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you: ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinning (anticoagulant) or steroid drug ● take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed. **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use if** you have ever had an allergic reaction to any other pain reliever/fever reducer. **Stop use and ask a doctor** if you experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), or if pain or fever gets worse. **If pregnant or breast-feeding**, ask a health professional before use. **Directions** Adults and children 12 years and older: take 1 tablet with water every 8 to 12 hours while symptoms last. For the first dose you may take 2 tablets within the first hour. Do not exceed 3 tablets in a 24-hour period. Children under 12 years: ask a doctor. **Questions or comments? 1-800-395-0689** (Mon-Fri 9AM – 5PM EST)

Dist. by:  
Bayer HealthCare LLC  
Whippany, NJ 07981

**86601648**

DRUG FACTS INFO: (Modified Format – updated 5/18/16)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	-
Drug Facts Continued	7 pt	-
Headings <sup>a</sup>	7 pt- <b>bold/italic</b> <sup>a</sup>	5 pt
Subheadings	≥6 pt	5 pt
Body Text	≥6 pt	5 pt
Bullets	5 pt	9 pt
Leading	≥0 pt	5.65 pt
Hairlines	0.5 pt rule	-
Box and Barlines <sup>f</sup>	>0.5 pt rule	-
Characters Per Inch:	No more than 39	> 39

<sup>a</sup> Headings are to be at least 2pts larger than Body Text.  
<sup>a</sup> Drug Facts Title to be larger than all other type size used in DPP  
<sup>f</sup> Box Barline may be omitted and color contrast used to highlight Drug Facts Info



FDA OIG 1817-1

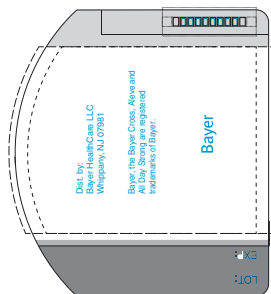
DRUG FACTS TABLE	REVISION	REVISION DATE	REVISION DESCRIPTION
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2	2	08/11/11	Initial release
3	3	08/11/11	Initial release
4	4	08/11/11	Initial release
5	5	08/11/11	Initial release
6	6	08/11/11	Initial release
7	7	08/11/11	Initial release
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95	95	08/11/11	Initial release
96	96	08/11/11	Initial release
97	97	08/11/11	Initial release
98	98	08/11/11	Initial release
99	99	08/11/11	Initial release
100	100	08/11/11	Initial release



200%



100%



2 tablets in a 6 to 12-hour period. Do not  
 exceed 3 tablets in a 24-hour period. Chosen  
 for use in patients with a creatinine clearance  
 of 30 mL/min or greater. Store at 20-25°C  
 (68-77°F). Avoid high humidity and  
 moisture. Do not use if the seal is broken or  
 if the tablets are discolored. Contains  
 100 mg of sodium. Contains 100 mg of  
 sodium. Contains 100 mg of sodium.

**See Caution For Full Information**  
 This product contains a nonsteroidal anti-inflammatory  
 drug (NSAID) which may cause side effects  
 including stomach pain, heartburn, dizziness,  
 headache, and drowsiness. See the full  
 information provided with this product for  
 a complete list of side effects.

**Heart attack and stroke warning:** NSAIDs, including  
 this product, may increase the risk of heart  
 attack and stroke. The risk is higher if you use this  
 product for a long time, at a high dose, or if you  
 have other risk factors for heart disease or  
 stroke. Tell your doctor if you have any of the  
 following conditions: heart disease, stroke,  
 high blood pressure, kidney disease, or  
 a history of stomach ulcers or bleeding.

FDA 020324-2  
 NDC 020324-2  
 Bayer HealthCare  
 Whippany, NJ 07981

Category	Drug Strength	Form of Drug
Tablets	100 mg	Tablet
Tablets	200 mg	Tablet
Tablets	250 mg	Tablet
Tablets	300 mg	Tablet
Tablets	350 mg	Tablet
Tablets	400 mg	Tablet
Tablets	450 mg	Tablet
Tablets	500 mg	Tablet
Tablets	550 mg	Tablet
Tablets	600 mg	Tablet
Tablets	650 mg	Tablet
Tablets	700 mg	Tablet
Tablets	750 mg	Tablet
Tablets	800 mg	Tablet
Tablets	850 mg	Tablet
Tablets	900 mg	Tablet
Tablets	950 mg	Tablet
Tablets	1000 mg	Tablet

Check this label with the full information leaflet.  
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 FDA requirements may vary by country.



DRUG FACTS INFO	REQUIRED	ACTUAL IN FILE
Category		
Drug Facts Title	≥8 pt.**	8 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings†	8 pt bold italic†	8 pt.
Subheadings	≥8 pt.	8 pt.
Body Text	≥8 pt.	8 pt.
Bullets	8 pt.	12 pt.
Lead-in	≥1.5 pt.	0.5 pt.
Footnotes	0.5 pt. min.	0.5 pt.
Box and Barlines†	≥0.5 pt. min.	2.5 pt.
Character's Per Inch	No more than 39†	≥39

\* Headings are to be at least 2x larger than Body Text.  
\*\* Drug Facts Title to be larger than all other type size used in ODP.  
† FDA Recommendations: 2, 5pt. min.



**Actual Size 100%**





FDA09182-1

DRUG FACTS TABLE		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	6 pt. min.	6 pt.
Drug Facts Content	6 pt.	6 pt.
Headings*	6 pt. bold text*	6 pt.
Subheadings	6 pt.	6 pt.
Body Text	6 pt.	6 pt.
Bullets	6 pt.	12 pt.
Linking	10.5 pt.	10.5 pt.
References	10.5 pt. min.	10.5 pt.
Images/Logos†	1/2" min. high	1/2"
Characters Per Inch	No more than 30	30†

\* If spacing, are to be at least 20% larger than Body Text.  
 † Only text. This table does not include all other text used in 2011 FDA submissions. Page 18



200%



100%

**Do not use if printed safety seal bearing Bayer red stripe is missing, cap is torn or missing.**

**See Caution For Full Information**

**Warnings**

**Allergic Reactions:** Naproxen sodium may cause a severe allergic reaction in some patients. Symptoms may include hives, facial swelling, asthma, wheezing, difficulty breathing, dizziness, fainting, or feeling lightheaded. Stop taking this medicine immediately if you experience any of these symptoms. Seek medical attention immediately. **1-800-393-6888** (Mond-Fri 9AM-5PM EST)

**Stomach Bleeding:** Stomach bleeding may occur with this medicine. The chance is higher if you: ● are age 65 or older ● take other drugs containing aspirin, ibuprofen, naproxen, or others ● use 3 or more alcoholic drinks every day while using this product ● take more or use longer than directed

**Heart Attack and Stroke Warnings:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer or for longer than directed. Do not use if you have heart disease, high blood pressure, kidney disease, or heart failure. Ask a doctor or pharmacist before use if you have a history of stomach problems such as ulcers, bleeding, or perforation. Do not use if you are taking or have taken any other drugs. When using this product take with food or milk if stomach upset occurs. Stop use and ask a doctor or pharmacist before use if you experience any of the following symptoms: ● black stools ● blood in stool or urine ● blood in vomit ● stomach pain that does not get better ● you have symptoms of heart problems or stroke

**Other Information:** ● Do not use if you are pregnant or trying to get pregnant. Do not use more than directed. ● Do not use if you are breastfeeding, or plan to breastfeed, for 3 months of pregnancy unless definitely directed to do so by a health professional before use. It is especially important to avoid use if you are breastfeeding because you may cause your baby harm. ● Do not use if you are taking or have taken any other drugs. When using this product take with food or milk if stomach upset occurs. Stop use and ask a doctor or pharmacist before use if you experience any of the following symptoms: ● black stools ● blood in stool or urine ● blood in vomit ● stomach pain that does not get better ● you have symptoms of heart problems or stroke

**Directions:** Do not take more than directed. The smallest effective dose should be used. Drink a full glass of water with each dose. For the first dose you may take 2 tablets with food in the morning. Do not exceed 12 tablets in 24 hours.

**Do not use if printed safety seal bearing Bayer red stripe is missing, cap is torn or missing.**

**See Caution For Full Information**

**Warnings**

**Allergic Reactions:** Naproxen sodium may cause a severe allergic reaction in some patients. Symptoms may include hives, facial swelling, asthma, wheezing, difficulty breathing, dizziness, fainting, or feeling lightheaded. Stop taking this medicine immediately if you experience any of these symptoms. Seek medical attention immediately. **1-800-393-6888** (Mond-Fri 9AM-5PM EST)

**Stomach Bleeding:** Stomach bleeding may occur with this medicine. The chance is higher if you: ● are age 65 or older ● take other drugs containing aspirin, ibuprofen, naproxen, or others ● use 3 or more alcoholic drinks every day while using this product ● take more or use longer than directed

**Other Information:** ● Do not use if you are pregnant or trying to get pregnant. Do not use if you are breastfeeding, or plan to breastfeed, for 3 months of pregnancy unless definitely directed to do so by a health professional before use. It is especially important to avoid use if you are breastfeeding because you may cause your baby harm. ● Do not use if you are taking or have taken any other drugs. When using this product take with food or milk if stomach upset occurs. Stop use and ask a doctor or pharmacist before use if you experience any of the following symptoms: ● black stools ● blood in stool or urine ● blood in vomit ● stomach pain that does not get better ● you have symptoms of heart problems or stroke

**Directions:** Do not take more than directed. The smallest effective dose should be used. Drink a full glass of water with each dose. For the first dose you may take 2 tablets with food in the morning. Do not exceed 12 tablets in 24 hours.

Lot #: 188881151  
EXP: 12/2017

Produced by:  
Bayer HealthCare LLC  
Whippany, NJ 07981

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**Bayer**

CONTENTS	REMOVED	ACTUAL IN USE
Day After Use	> 7.5%	-
Hourly	7.5% - 15%	5.5%
15-Minute	15% - 30%	12.5%
30-Minute	30% - 45%	15%
Hourly	45% - 60%	15%
Day After Use	> 60%	-
Hourly	60% - 75%	55%

Manufactured by Bayer HealthCare LLC, Whippany, NJ 07981. © 2017 Bayer HealthCare LLC. All rights reserved. This is a registered trademark of Bayer HealthCare LLC. All other trademarks are the property of their respective owners. Do not use if you are pregnant or trying to get pregnant. Do not use if you are breastfeeding, or plan to breastfeed, for 3 months of pregnancy unless definitely directed to do so by a health professional before use. It is especially important to avoid use if you are breastfeeding because you may cause your baby harm. Do not use if you are taking or have taken any other drugs. When using this product take with food or milk if stomach upset occurs. Stop use and ask a doctor or pharmacist before use if you experience any of the following symptoms: ● black stools ● blood in stool or urine ● blood in vomit ● stomach pain that does not get better ● you have symptoms of heart problems or stroke.

LOT & EXP. AREA

Made in USA

**SOFT GRIP® ARTHRITIS CAP**

ALL DAY STRONG®

# ALEVE

Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

**Drug Facts (continued)**

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

**Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

**When using this product**

- take with food or milk, if stomach upset occurs

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

**Drug Facts (continued)**

**If pregnant or breast-feeding,** ask a health professional for one use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

**Adults and children 12 years and older**

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period
- ask a doctor

**Children under 12 years**

- ask a doctor

**Other information**

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

**Inactive ingredients:** D&C yellow #10 aluminum lake, edetate disodium, red ink, FD&C blue #1, FD&C yellow #6 aluminum lake, gelatin, glycerin, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, potassium, stearic acid, lacte, titanium dioxide

**Questions or comments? 1-800-395-0689**  
(Mon-Fri 9AM-5PM EST)

**Drug Facts**

**Active ingredient (in each tablet)**

Naproxen sodium 220 mg  
Naproxen 200 mg (NSAID) \_\_\_\_\_ Pain reliever/fever reducer, nonsteroidal anti-inflammatory drug

**Purposes**

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscular aches
  - backache
  - menstrual cramps
  - headache
  - toothache
  - the common cold
- temporarily reduces fever

**Uses**

- temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscular aches
  - backache
  - menstrual cramps
  - headache
  - toothache
  - the common cold
- temporarily reduces fever

**Warnings**

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin redness
- rash
- dizziness

If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

THIS PACKAGE IS CHILD-RESISTANT



**STRENGTH TO LAST 12 HOURS**

40 GELCAPS  
GELATIN COATED CAPSULE-SHAPED TABLETS

00000000

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Dist. by  
Bayer HealthCare LLC



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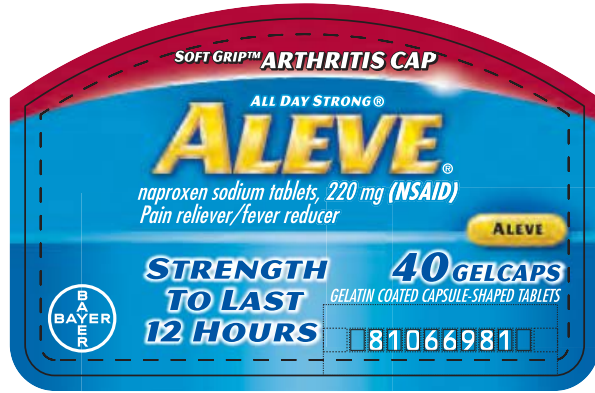
PS

FDA00204-1

DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	≥8 pt.**	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings†	8 pt.-bold italic‡	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.2 - 0.5 pt.
Headlines	0.5 pt. rule	0.5pt.
Box and Barline†	≥0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 35	≤ 35

† Headings are to be at least 50% larger than Body Text.  
\*\* Drug Facts Title to be larger than all other text used in DFP.  
†† FDA Recommends 2.5pt. rule.

200%



100%



**LOT:** [blacked out]

**EXP:** [blacked out]

**Keep out of reach of children.** Use only as directed. For more information, see the Important Information on this product's packaging.

**Caution:** This contains higher iron levels. Avoid iron supplements or iron-enriched foods and beverages if you are taking this product. Tell your doctor if you are taking a medicine, you have a condition that affects iron metabolism, or you are taking a medicine, you have a condition that affects iron metabolism, or you are taking a medicine, you have a condition that affects iron metabolism.

**Warnings:** Tell your doctor if you are taking a medicine, you have a condition that affects iron metabolism, or you are taking a medicine, you have a condition that affects iron metabolism.

**Keep out of reach of children.** Use only as directed. For more information, see the Important Information on this product's packaging.

**Caution:** This contains higher iron levels. Avoid iron supplements or iron-enriched foods and beverages if you are taking this product. Tell your doctor if you are taking a medicine, you have a condition that affects iron metabolism, or you are taking a medicine, you have a condition that affects iron metabolism.

**Warnings:** Tell your doctor if you are taking a medicine, you have a condition that affects iron metabolism, or you are taking a medicine, you have a condition that affects iron metabolism.

**Keep out of reach of children.** Use only as directed. For more information, see the Important Information on this product's packaging.

**Caution:** This contains higher iron levels. Avoid iron supplements or iron-enriched foods and beverages if you are taking this product. Tell your doctor if you are taking a medicine, you have a condition that affects iron metabolism, or you are taking a medicine, you have a condition that affects iron metabolism.

UNIT FACTS INFP	Category	Required	Actual in File
Days Pieces Box		30 or 90	-
Days Pieces Container		30 or 90	-
Heavyweight		8 or 20 mg tablet*	6 or 6
Subpackages		30 or 90	6 or 6
Box Weight		5.0 or 5.0	5.0 or 5.0
Box Length		5.0 or 5.0	5.0 or 5.0
Box and Blister*†		5.0 or 5.0	-
Days Pieces Per Unit		More than 30	< 30

\* Heavyweight or subpackage weight does not refer to the box, but to the individual unit or container.  
† FDA Measurement 2, 3, 4, etc.

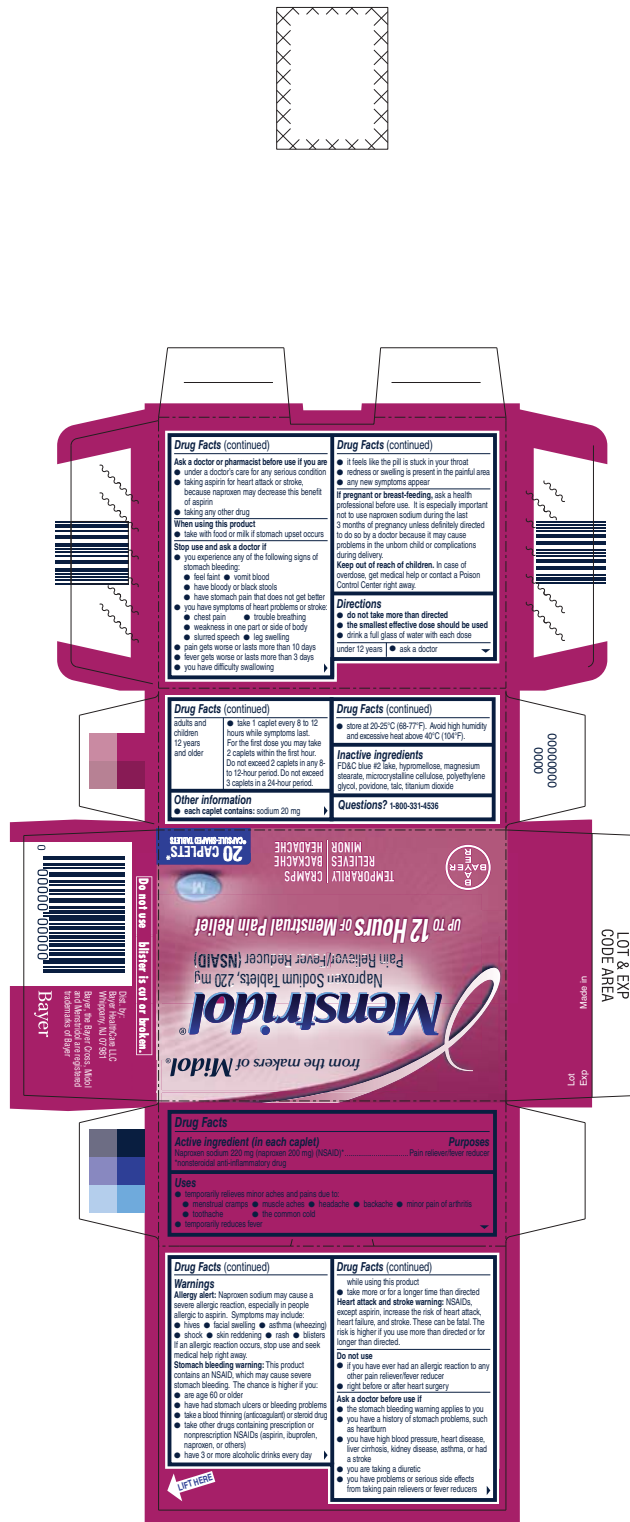


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100%





FDA00245-2

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings <sup>†</sup>	8 pt bold italic*	8 pt.
Subheadings	<8 pt.	5 pt.
Bullet Text	<8 pt.	8 pt.
Bullets	5 pt.	12 pt.
Leading	<0.5 pt.	0.5 pt.
Headlines	0.5 pt rule	0.5 pt.
Box and Barlines	>0.5 pt rule	2.5 pt.
Characters Per Inch:	No more than 38†	<38

<sup>†</sup> Headings are to be at least 24pt larger than Body Text.  
<sup>\*\*</sup> Drug Facts Title is to be larger than all other type size used in DDP.  
 † FDA Requirements 2 for rule.



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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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NUSHIN F TODD  
04/23/2020 04:14:39 PM