

Drug Facts (continued)

- 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 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 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

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

Drug Facts

Active ingredient Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)

Purposes Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - minor pain of arthritis
 - muscular aches
 - backache
 - 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, facial swelling, asthma (wheezing), shock, skin redness, rash, blisters.

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.

Strength to Last 12 Hours

24 TABLETS

LOT EXP MADE IN Bayer

LOT & EXP CODE AREA

Actual Size 100%

FDA00332-2

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†	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.	6.2 - 6.5 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 20% larger than Body Text.
 ** Drug Facts Title to be larger than all other types used in DFP.
 † FDA Recommends 2.5pt rule.
 ‡ Box and Barlines

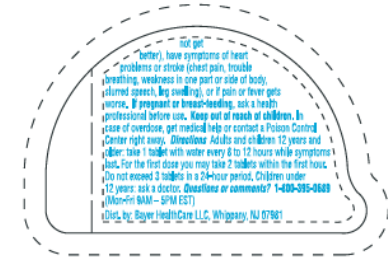
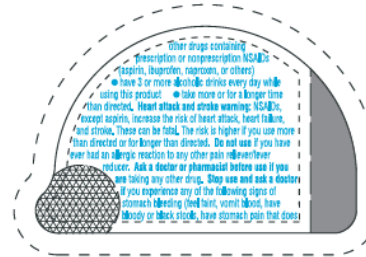
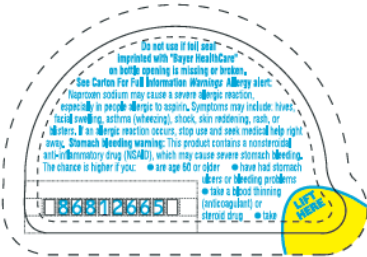


200%



Actual Size 100%

FDA00329-1



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- 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	NA
Barlines‡	> 0,5 pt rule	NA

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.
‡ FDA recommends size 2,5 pt type



Actual Size 100%

FDA00333-2

DRUG FACTS INFO <small>Updated 5/18/18</small>		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	9 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.	6.0 - 6.5 pt.
Hair lines	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 2pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DPP.
† FDA recommends 2.5pt rule.

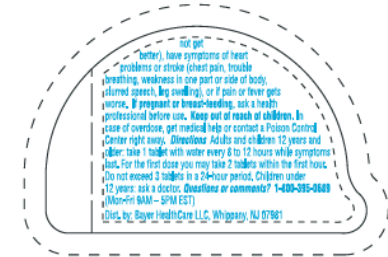
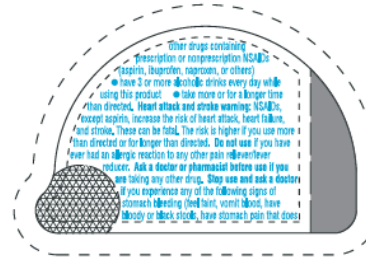
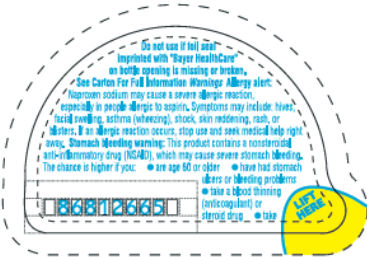


200%



Actual Size 100%

FDA00330-1



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- 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	NA
Barlines†	> 0,5 pt rule	NA

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.
† FDA recommends size 2,5 pt type



Actual Size 100%

FDA00334-2

DRUG FACTS INFO (Updated 5/19/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	9 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	6 pt.	12 pt.
Leading	≥0.5 pt.	6.5 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 20% larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP.
‡ FDA recommends 2.5pt rule.



200%



Actual Size 100%

FDA00331-2



DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL ON FILE
Drug Facts Title	>8 pt.**	-
Drug Facts Continued	8 pt.	-
Headings*	8 pt-bold italic*	4,5 pt.
Subheadings	≥6 pt.	4,5 pt.
Body Text	≥6 pt.	4,5 pt.
Bullets	5 pt.	6 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

* Headings are to be at least 2 pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP
† FDA Recommends 2,5pt rule



Actual Size 100%

FDA00335-1

DRUG FACTS INFO <small>updated 5/18/18</small>		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	9 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	6.8 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 20% larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DPP
† FDA Recommends 2.5pt rule



200%



Actual Size 100%

FDA00336-2

See Center for Full Information

Warning: 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 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 the 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 disease, 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: • Use printed table with food or on an empty stomach as directed. 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 pain), pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, you have difficulty swallowing, 1 tablet 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 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. 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). **Use of this or contents?** 1-800-318-1888 (Mon-Fri 9AM - 5PM EST)

Made by Bayer HealthCare LLC
Whispery, NJ 07081

Actual Size 100%

FDA00337-1

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
Hair lines	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

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.

/s/

NUSHIN F TODD
12/31/2020 10:36:36 AM