



DRUG FACTS INFO: Modified Format - updated 5/18/19		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	7.5 pt
Drug Facts Continued	7 pt	7 pt
Headings ¹	7 pt-bold italic ²	7 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0 pt	0 - 0.6 pt
Hairlines	0.5 pt rule	0.5 pt
Box and Barlines ³	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 39	≤ 39

¹ Headings are to be at least 1st larger than Body Text
² Drug Facts Title to be larger than all other type size used in DPP
³ Box Barlines may be omitted and color contrast used to highlight Drug Facts title

88368517



Do not use if carton is open or if foil seal imprinted with Bayer HealthCare on bottle opening is missing or broken.

Drug Facts (continued)

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- unless you have time for a full night's sleep
- in children under 12 years of age
- right before or after heart surgery
- with any other product containing diphenhydramine, even one used on skin
- if you have sleeplessness without pain

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- 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 a breathing problem such as emphysema or chronic bronchitis
- you have glaucoma
- you have trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers, or any other sleep-aid
- 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 antihistamines
- taking any other drug

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- 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 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

Drug Facts (continued)

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
- it feels like the pill is stuck in your throat

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in 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
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets at bedtime
- do not take more than 2 caplets in 24 hours
- if taken with food, this product may take longer to work

Other information

- read all warnings and directions before use. Keep outer carton.
- 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 carnauba wax, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, purified water, talc, titanium dioxide

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

Drug Facts

Active ingredients Purposes (in each caplet)

Diphenhydramine hydrochloride 25 mg Nighttime sleep-aid
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)* Pain reliever
*nonsteroidal anti-inflammatory drug

Uses

- for relief of occasional sleeplessness when associated with minor aches and pains
- helps you fall asleep and stay asleep

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
- 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
- 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.



**naproxen sodium, 220 mg (NSAID)/
diphenhydramine HCl, 25 mg**
Pain reliever/nighttime sleep-aid



**SLEEP AID
PLUS 12 HOUR PAIN
RELIEVING STRENGTH
OF ALEVE**

ACTUAL SIZE

**50
CAPLETS***
*CAPSULE-SHAPED TABLETS

Bayer, the Bayer Cross and Aleve are registered trademarks of Bayer.
Dist. by:
Bayer HealthCare LLC, Whippany, NJ 07981
MADE IN GERMANY

LOT/EXP Bayer

8517



QUIET ZONE

DRUG FACTS INFO: (Modified Format - updated 5/11/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	8.1 pt
Drug Facts Continued	7 pt	8 pt
Headings ¹	7 pt-bold italic ²	8 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0 pt	0 pt
Hairlines	0.5 pt rule	0.5 pt
Box and Barlines ³	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤ 39

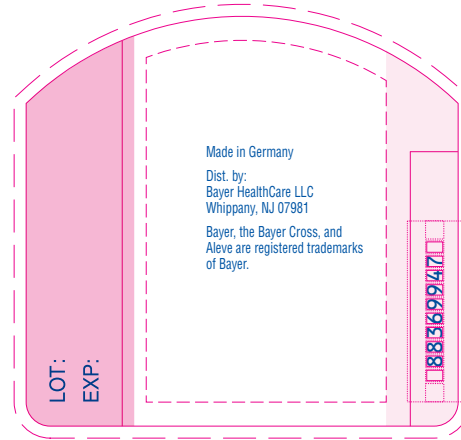
¹ Headings are to be at least 1pt larger than Body Text.
² Drug Facts Title to be larger than all other type size used in DFP.
³ Box Barlines may be omitted and color contrast used to highlight Drug Facts Info.



200%



Actual Size 100%



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

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Drug Facts

Active Ingredients (in each caplet)

Diphenhydramine hydrochloride 25 mg..... Nighttime sleep-aid
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)Pain reliever
*nonsteroidal anti-inflammatory drug

Questions or comments? 1-800-985-0888
(Mon-Fri 9AM - 5PM EST)

Bayer

Drug Facts (continued)

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
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
- it feels like the pill is stuck in your throat

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in 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
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets at bedtime
- do not take more than 2 caplets in 24 hours
- if taken with food, this product may take longer to work

Other information

- read all warnings and directions before use.
- 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 carnauba wax, FD&C blue #2, aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, purified water, tac, titanium dioxide

Drug Facts (continued)

Uses

- for relief of occasional sleeplessness when associated with minor aches and pains
- helps you fall asleep and stay asleep

Warnings

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

- hives ● asthma (wheezing) ● facial swelling
- skin redness ● shock ● 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
- 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
- unless you have time for a full night's sleep
- in children under 12 years of age
- right before or after heart surgery
- with any other product containing diphenhydramine, even one used on skin
- if you have sleeplessness without pain

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- 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 a breathing problem such as emphysema or chronic bronchitis
- you have glaucoma
- you have trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers, or any other sleep-aid
- 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 antihistamines
- taking any other drug

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- take with food or milk if stomach upset occurs

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.	0.5 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 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%

Effects from taking pain relievers or fever reducers • 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 a breathing problem such as emphysema or chronic bronchitis • you have glaucoma • you have trouble urinating due to an enlarged prostate gland. **When using this product** • drowsiness will occur • avoid alcoholic drinks • do not drive a motor vehicle or operate machinery • take with food or milk if stomach upset occurs. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). **If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Directions Do not take more than directed.** Adults and children 12 years and over: take 2 caplets with a full glass of water at bedtime. Do not take more than 2 caplets in 24 hours. **Other information • each caplet contains:** sodium 20 mg. **Questions or comments? † 1-800-395-0689** Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981

LOT:
EXP:

88884860

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

Active ingredients (in each caplet) Diphenhydramine hydrochloride 25 mg, Naproxen sodium 220 mg (naproxen 200 mg) **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 • 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.**

LIFT
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• unless you have time for a full night's sleep

• in children under 12 years of age • right before or after heart surgery • with any other product containing diphenhydramine, even one used on skin • if you have sleeplessness without pain **Ask a doctor or pharmacist before use if you are** • taking sedatives or tranquilizers, or any other sleep-aid • under a doctor's care for any serious condition • taking any other antihistamines • taking any other drug **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 • sleeplessness persists continuously for more than 2 weeks (Insomnia may be a symptom of a serious underlying medical illness) • redness or swelling is present in the painful area • any new symptoms appear • you have difficulty swallowing • it feels like the pill is stuck in your throat **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Ask a doctor before use if** • stomach bleeding warning applies to you • you have problems or serious side

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt [‡]	N/A
Drug Facts Continued	7 pt [‡]	N/A
Headings	7 pt-bold italic [‡]	5 pt
Subheadings	6 pt [‡]	5 pt
Body Text	6 pt [‡]	5 pt
Bullets	5 pt	4 pt
Hairlines	0.5 pt rule	N/A
Barlines [†]	> 0.5 pt rule	N/A

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/

VALERIE S PRATT
02/08/2022 02:46:13 PM