



200%

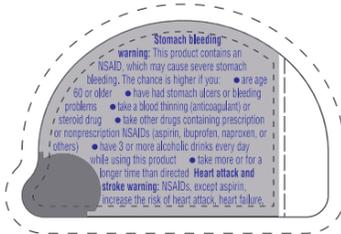


**Actual Size 100%**

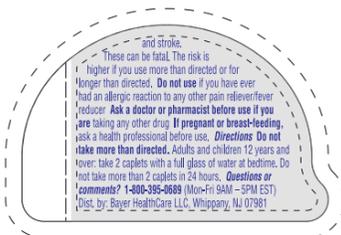
FDA00290-1



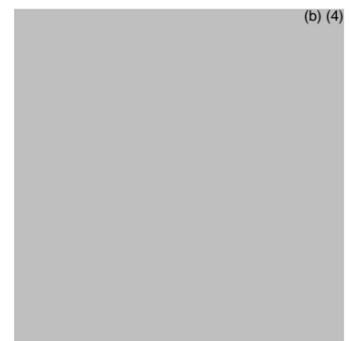
Panel 1 Top



Panel 2 Inside



Panel 3 Base



(b) (4)



**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 ● 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

**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.

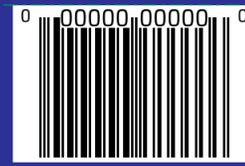
**Directions** ● do not take more than directed ● drink a full glass of water with each dose ● adults and children 12 years and over: take 2 caplets at bedtime ● do not take more than 2 caplets in 24 hours ● if taken with food, this product may take longer to work

**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** camauba 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)

Bayer



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



**ALEVE**  
**pm**

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



ALEVE pm

ACTUAL SIZE

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

**20  
CAPLETS\***

\*CAPSULE-SHAPED TABLETS

Dist. by:  
Bayer HealthCare LLC  
Whippany, NJ 07981

Bayer, the Bayer Cross and Aleve are registered trademarks of Bayer.

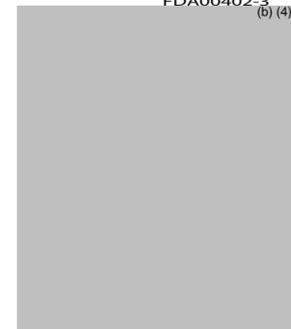
LOT/EXP



LOT & EXP  
CODE AREA

**Actual Size 100%**

FDA00402-3  
(b) (4)





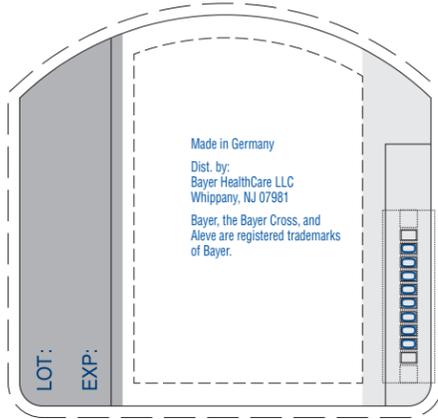
200%



**Actual Size 100%**

FDA00276-2

**Actual Size 100%**



(b) (4)

**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)
- skin redness
- facial swelling
- 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 (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 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**
- 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, talc, titanium dioxide

**Questions or comments? 1-800-545-0088**  
(Mon-Fri 9AM - 5PM EST)

Bayer

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

**Drug Facts**

Active Ingredients (in each caplet)	Purposes
Diphenhydramine hydrochloride 25 mg	Nighttime sleep-aid
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)	Pain reliever
*nonsteroidal anti-inflammatory drug	



200%



**Actual Size 100%**

FDA00294-1

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 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. **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: \_\_\_\_\_

086030128

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

LIFT  
 HERE

- 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: (red, black, or tarry stool, or 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



(b) (4)





200%

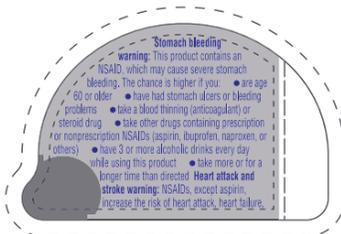


**Actual Size 100%**

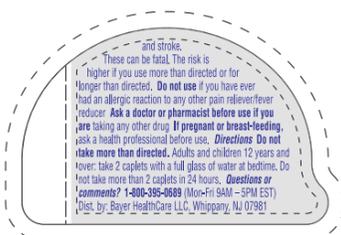
FDA00287-1



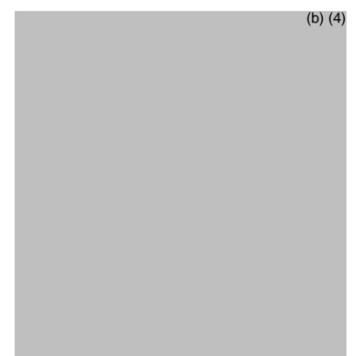
Panel 1 Top



Panel 2 Inside



Panel 3 Base



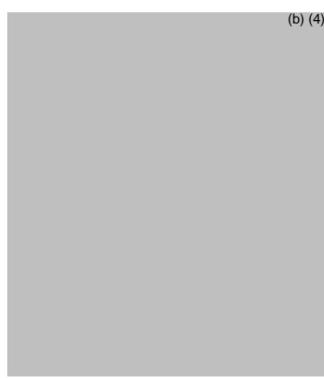
(b) (4)



LOT & EXP CODE AREA

Actual Size 100%

FDA00286-3



-----  
**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  
10/30/2020 03:45:54 PM