

**NAPROXEN SODIUM DIPHENHYDRAMINE HYDROCHLORIDE- naproxen sodium
diphenhydramine hydrochloride tablet
SAFEWAY**

**Pain Relief PM
Naproxen Sodium and Diphenhydramine HCL Tablets
220mg/25mg (NSAID)****

**Pain Reliever/Nighttime sleep-aid
SLEEP AID PLUS
12 HOURS PAIN RELIEVING**

Active Ingredients (in each caplet)

Diphenhydramine Hydrochloride 25mg

Naproxen Sodium 220mg

Purpose

Pain Reliever/Nighttime sleep-aid

Sleep Aid Plus

Uses

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

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
- 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

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 the 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

■ each caplet contains: **sodium** 20mg

■ **read all warnings and directions before use.**

Keep outer carton.

■ store at 20 to 25 °C (68 to 77 °F)

■ avoid high humidity and excessive heat above 40 °C (104 °F)

Inactive ingredients

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

Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

PDP

LOT#	:
COS#	:
SIZE	: 11/3/4 X 11/3/4 X 3/3/8
REF #	: 221905048
MATERIAL	: 1.015 303
VI	:
DU	:

Drug Facts (continued)


Other information Each caplet contains sodium 20 mg. **Read all warnings and directions before use. Keep outer carton, in store at 20 to 25°C (68 to 77°F) avoid high humidity and excessive heat above 40°C (104°F).**

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

Questions or comments?
Call 1-877-770-8183 Mon-Fri 8:00 AM EST to 8:00 PM PST.

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Quality Guaranteed

Compare to ALEVE® pm
with ingredients*

NDC 21130-814-05

Pain Relief PM

Naproxen Sodium and Diphenhydramine HCl Tablets

220 mg/25 mg (NSAID)**

Pain Reliever/Nighttime sleep-aid


• SLEEP AID PLUS

• 12 HOURS PAIN RELIEVING

50 CAPLETS*

*CAPSULE-SHAPED TABLETS

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COATING FREE AREA

Drug Facts (continued)

When using this product:

- avoid alcohol or avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery while with food or right after stomach upset occurs

Stop use and ask a doctor if:

- you experience any of the following signs of stomach bleeding:
 - feel lightheaded or dizzy
 - vomit blood or 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
- you get worse or have more than 2 days
- dizziness persists continuously for more than 2 weeks.

Warnings:

- **Aspirin may be a symptom of a sudden underlying medical illness. Address or swelling is present in the painful area.**
- you have any symptoms appear
- you have difficulty swallowing
- you feel like the pill is stuck in your throat
- you are pregnant or breastfeeding, with a health professional before use, it is especially important not to use naproxen sodium during the last 3 months of pregnancy unless absolutely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.
- **Keep out of the 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
- take 2 capsules of bedtime
- do not take more than 2 capsules in 24 hours
- if taken with food, this product may take longer to work

COATING FREE AREA

Drug Facts (continued)

Do not use:

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- unless you have been told by a health care provider
- 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 dizziness without pain

Ask a doctor before use if:

- you are taking any other medicine
- 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 disease, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have a bleeding problem such as emphysema or chronic bronchitis
- you have diabetes
- you have had difficulty swallowing due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are:

- taking medicines or supplements or any other sleep-aid
- under a doctor's care for any medical condition
- taking aspirin for heart attacks or stroke, because aspirin may increase this benefit of aspirin
- taking any other alcohol or medicine
- taking any other drug

COATING FREE AREA

NAPROXEN SODIUM DIPHENHYDRAMINE HYDROCHLORIDE			
naproxen sodium diphenhydramine hydrochloride tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-814
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
NAPROXEN SODIUM (UNII: 9TN8753A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg	

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)
(DIPHENHYDRAMINE - UNII:8GTS82S83M)

DIPHENHYDRAMINE
HYDROCHLORIDE

25 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	G;17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-814-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213663	06/30/2023	

Labeler - SAFEWAY (009137209)

Revised: 12/2025

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