NAPROXEN SODIUM DIPHENHYDRAMINE HCL- naproxen sodium diphenhydramine hcl tablet, film coated
WALGREEN CO.

NAPROXEN SODIUM PM

Naproxen Sodium & 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 25 mg

Naproxen Sodium 220 mg (naproxen 200 mg) (NSAID)*

Purposes

Nighttime sleep aid

Pain reliever

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 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 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

• each caplet contains: **sodium** 20 mg
• **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?

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

Naproxen Sodium & Diphenhydramine HCl 220mg/25mg

NAPROXEN SODIUM DIPHENHYDRAMINE HCL

naproxen sodium diphenhydramine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-9766
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL (modified capsule shaped biconvex film coated tablet)	**Size**	15mm
Flavor		**Imprint Code**	G;17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9766-08	80 in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2021	09/30/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213663	06/19/2021	09/30/2025

Labeler - WALGREEN CO. (008965063)

Revised: 1/2024 WALGREEN CO.