NAPROXEN SODIUM AND DIPHENHYDRAMINE HCL- naproxen sodium and diphenhydramine hcl tablet
TARGET CORPORATION

Naproxen Sodium PM
220mg Naproxen Sodium/ 25mg Diphenhydramine HCL Tablets
Pain reliever (NSAID)/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)*
* nonsteroidal anti-inflammatory drug

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?

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

Principal display panel

NAPROXEN SODIUM AND DIPHENHYDRAMINE HCL

naproxen sodium and diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11673-819
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

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:11673-819-08	80 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213663	03/01/2024	

Labeler - TARGET CORPORATION (006961700)

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