EQUATE ALL NIGHT PAIN RELIEF- diphenhydramine hydrochloride, naproxen sodium tablet, film coated Wal-Mart Stores Inc

Wal-Mart All Night Pain Relief Drug Facts

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

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
- 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 reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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 21 mg
- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)

Inactive ingredients

croscarmellose sodium, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, talc, titanium dioxide

Questions or comments?

1-888-287-1915

Package/Label Principal Display Panel

equate[™]

Compare to Aleve[®] pm active ingredients

All Night Pain Relief

Naproxen Sodium and Diphenhydramine Hydrochloride Tablets, 220 mg/25 mg

Sleep Aid Plus 12-Hour Pain Reliever

Pain reliever (NSAID)/Nighttime Sleep-aid

20 CAPLETS**

**Capsule-Shaped Tablets

Actual Size



Ρ	roduct Informa	tion							
P	roduct Type		HUMAN OTC	DRUG	Item Code	(Source)	NDC:490	35-727	
Route of Administration		ation	ORAL		item coue			5.45055727	
R	oute of Administr	ation	UNAL						
A	ctive Ingredien	t/Active	Moiety						
		Ingre	dient Nam	е		Basis of S	trength	Strengt	
DIPHENHYDRAMINE HYDROC (DIPHENHYDRAMINE - UNII:8GTS)			LORIDE (UNII: TC2D6JAD40)			DIPHENHYDRAMINE HYDROCHLORIDE		25 mg	
NA	APROXEN SODIUM (JNII: 9TN87	S3A3C) (NAPF	ROXEN - UNII:5	7Y76R9ATQ)	NAPROXEN SOD	IUM	220 mg	
In	active Ingredie	ents							
			Ingredi	ent Name			S	trength	
CF	ROSCARMELLOSE S	ODIUM (UN	II: M280L1HH	48)					
FC	O&C BLUE NO. 1 (UN	III: H3R47K3	BTBD)						
FC	&C BLUE NO. 2 (UN	III: L06K8R7	DQK)						
M	AGNESIUM STEARAT	r e (UNII: 70	097M6I30)						
м	CROCRYSTALLINE (CELLULOSI	E (UNII: OP1R	32D61U)					
PC	LYETHYLENE GLYC	OL, UNSPE	ECIFIED (UNI	I: 3WJQ0SDW1A	4)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)									
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)									
SI	LICON DIOXIDE (UNI	I: ETJ7Z6XB	SU4)						
TALC (UNII: 7SEV7J4R1U)									
тľ	TANIUM DIOXIDE (U	NII: 15FIX9V	′2JP)						
Pı	roduct Charact	eristics							
Сс	olor	BL	UE	Score		r	no score		
Sł	nape	٥V	/AL	Size		1	.5mm		
	avor			Imprint Cod	de	L	264		
FI	ontains								
Co	ackaging								
Co	ackaging Item Code	Pa	ckage Des	cription	Mar	keting Start Date		ting End ate	
Pa	Item Code	Pac n 1 CARTON	-	cription	Mar 04/20/2	Date			

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208499	04/20/2020	

Labeler - Wal-Mart Stores Inc (051957769)

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Wal-Mart Stores Inc