

**NAPROXEN SODIUM AND DIPHENHYDRAMINE HCL- naproxen sodium and diphenhydramine hcl tablet, film coated**  
**Granules India Ltd**

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**Naproxen Sodium and Diphenhydramaine HCl Tablets**

**ACTIVE INGREDIENT(S)**

Diphenhydramine Hydrochloride 25 mg  
Naproxen Sodium 220 mg (naproxen 200 mg) (NSAID)\*  
\* nonsteroidal anti-inflammatory drug

**PURPOSE**

Night time sleep aid  
Pain reliever

**USE(S)**

- 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 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, Drug Facts Drug Facts 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**

- 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 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 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 BREASTFEEDING**

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 to 25°C (68 to 77°F).
- avoid high humidity and excessive heat above 40°C (104°F).
- **Tamper Evident: Do not use if foil inner seal under the cap is opened or missing**

### **INACTIVE INGREDIENTS**

FD&C blue2 aluminum lake, hypromellose, magnesiumstearate, microcrystalline cellulose,

polyethyleneglycol, povidone, talc, titanium dioxide.

**QUESTIONS OR COMMENTS ?**

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

**PRINCIPAL DISPLAY PANEL**

**Naproxen Sodium and  
Diphenhydramine HCl Tablets  
220 mg/25 mg (NSAID)**

Pain Reliever/Nighttime sleep-aid

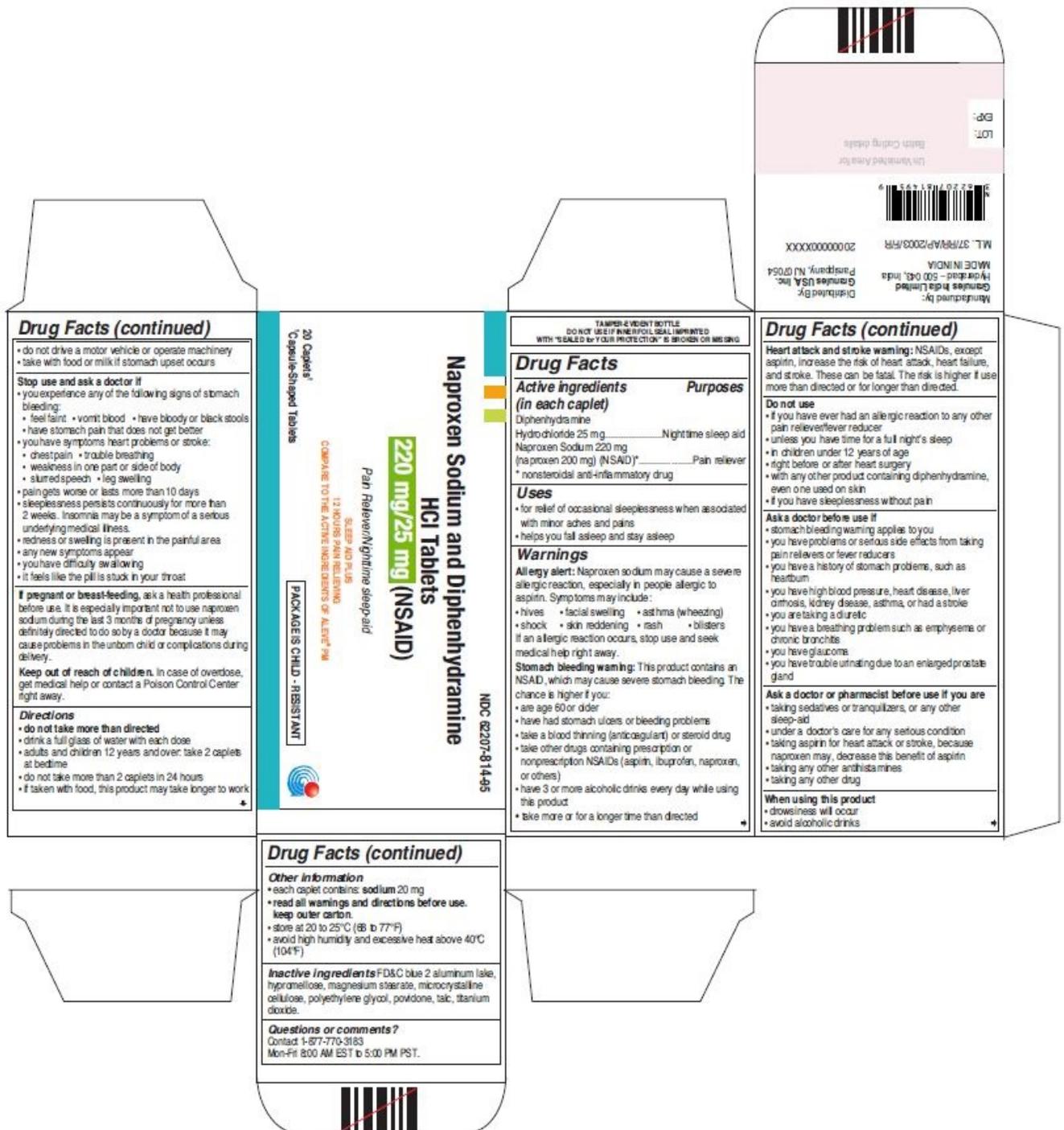
**SLEEP AID PLUS**

**12 HOUR PAIN RELIEVING**

**COMPARE TO THE ACTIVE INGREDIENTS OF ALEVE PM**

20 Caplets †

†Capsule-Shaped Tablets



## PRINCIPAL DISPLAY PANEL

# Naproxen Sodium and Diphenhydramine HCl Tablets 220 mg/25 mg (NSAID)

Pain Reliever/Nighttime sleep-aid

**SLEEP AID PLUS**

**12 HOUR PAIN RELIEVING**

**COMPARE TO THE ACTIVE INGREDIENTS OF ALEVE PM**



# Naproxen Sodium 220 mg and Diphenhydramine Hydrochloride 25 mg Tablets

Each Tablet contains Naproxen Sodium USP 220mg and Diphenhydramine Hydrochloride USP 25 mg

Batch No. : XXXXXXXX

No. of Tablets : 7500

Mfg. Dt. : YYYY/MM

Exp. Dt. : YYYY/MM

Mfg.Lic.No. : 37/RR/AP/2003/F/R

NDC No. : 62207-814-39

Storage : Store at 20°C to 25°C (68°F to 77°F) (See USP controlled Room Temperature).

Caution :For repacking only.

Country of Origin: INDIA

FG Code: 700000002498

## NAPROXEN SODIUM AND DIPHENHYDRAMINE HCL

naproxen sodium and diphenhydramine hcl tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-814
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>HYPROMELLOSE 2910 (3 MPA.S)</b> (UNII: 0VUT3PMY82)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**HYPROMELLOSE 2910 (6 MPA.S)** (UNII: 0WZ8WG20P6)

**FD&C BLUE NO. 2--ALUMINUM LAKE** (UNII: 4AQJ3LG584)

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-814-95	1 in 1 CARTON	02/20/2021	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:62207-814-47	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/20/2021	
3	NDC:62207-814-38	37500 in 1 POUCH; Type 0: Not a Combination Product	02/20/2021	
4	NDC:62207-814-39	7500 in 1 POUCH; Type 0: Not a Combination Product	02/20/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213663	02/20/2021	

**Labeler** - Granules India Ltd (915000087)

Revised: 8/2025

Granules India Ltd