NAPROXEN SODIUM AND DIPHENHYDRAMINE HCL- naproxen sodium and diphenhydramine tablet, film coated
Amneal Pharmaceuticals NY LLC

Naproxen Sodium and Diphenhydramine HCl Tablets

Drug Facts

Active ingredients (in each tablet)

Diphenhydramine hydrochloride 25 mg

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

*nonsteroidal anti-inflammatory drug

Purposes

- Night time 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 non-prescription 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 at 20 weeks or later in 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 tablets at bedtime
- do not take more than 2 tablets in 24 hours
- if taken with food, this product may take longer to work

Other information

- read all warnings and directions before use.
- each tablet 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)

Inactive ingredients

carnauba wax, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc and titanium dioxide.

Questions or comments?

1-877-835-5472 (Mon – Fri 9AM – 5PM EST)

Manufactured by:
Amneal Pharmaceuticals Pvt. Ltd.
Oral Solid Dosage Unit
Ahmedabad 382213, INDIA

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Rev. 09-2022-02

Principal Display Panel

NDC 69238-1422-6

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

Rx only

160 Tablets

Amneal Pharmaceuticals LLC

12 MM BLANK FOR GLUE

NDC 69238-**1422**-6

Naproxen Sodium and Diphenhydramine HCl Tablets

220 mg/25 mg

Pain Reliever (NSAID)/
Nighttime Sleep-Aid

160 Tablets

amneal®

10 MM BLANK FOR GLUE

Do not use if printed foil under cap is broken or missing.

Mfg. Lic. No. G/25/2137

Manufactured by:
Amneal Pharmaceuticals Pvt. Ltd.
Oral Solid Dosage Unit
Ahmedabad 382213, INDIA

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Rev. 09-2022-02

N 3 69238 14226 6

Non-Varnish Area
(For Lot And Exp. Date
(24 x 54 mm)

PEEL HERE

PEEL BACK FOR ADDITIONAL DRUG FACTS

NDC 69238-**1422**-6

Naproxen Sodium and Diphenhydramine HCl Tablets

220 mg/25 mg

Pain Reliever (NSAID)/
Nighttime Sleep-Aid

160 Tablets

amneal®

10 MM BLANK FOR GLUE

Drug Facts (continued)

Page 4 of 5

- 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 at 20 weeks or later in 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**

Drug Facts (continued)

Page 5 of 5

- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 tablets at bedtime
- do not take more than 2 tablets in 24 hours
- if taken with food, this product may take longer to work

Other information

- read all warnings and directions before use.
- each tablet 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)

Inactive ingredients

carnauba wax, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc and titanium dioxide.

Questions or comments?

1-877-835-5472 (Mon – Fri 9AM – 5PM EST)

Drug Facts

Page 1 of 5

Active ingredients (in each tablet) ***Purposes***

Diphenhydramine hydrochloride 25 mg ..... Nighttime sleep-aid
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)* ..... Pain reliever
*nonsteroidal anti-inflammatory drug

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

Drug Facts (continued)

Page 2 of 5

thinning (anticoagulant) or steroid drug • take other drugs containing prescription or non-prescription 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

Drug Facts (continued)

Page 3 of 5

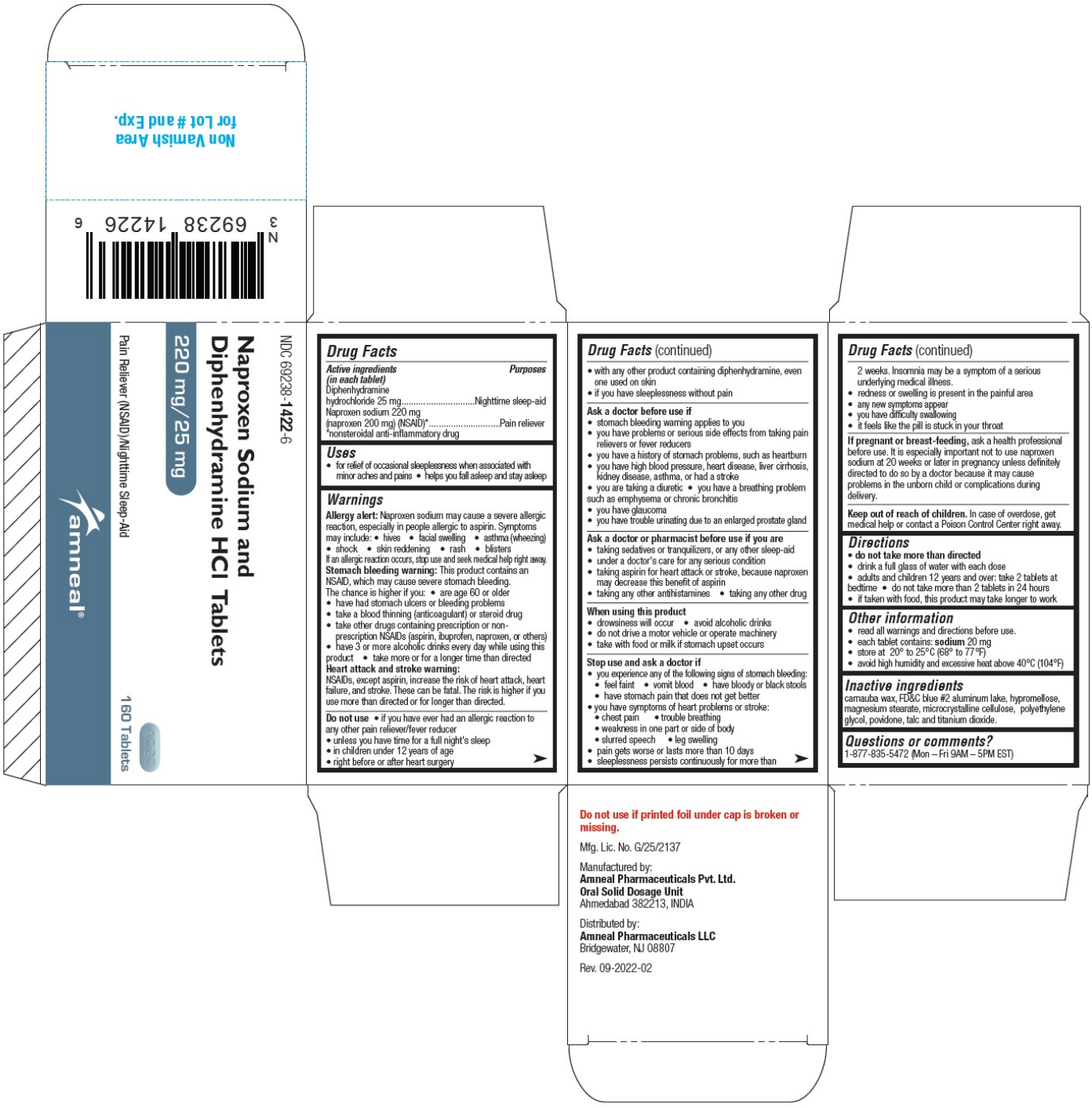
Ask a doctor or pharmacist before use if you are
- taking sedatives or tranquilizers, or any other sleep-aid • under a doctor's care for any serious condition • taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin • taking any other antihistamines • taking 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

SEE BACK FOR ADDITIONAL DRUG FACTS

12 MM BLANK FOR GLUE



NAPROXEN SODIUM AND DIPHENHYDRAMINE HCL

naproxen sodium and diphenhydramine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69238-1422
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (Light Blue)	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	AC37
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69238-1422-2	1 in 1 CARTON	10/23/2018	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69238-1422-4	1 in 1 CARTON	10/23/2018	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69238-1422-8	1 in 1 CARTON	10/23/2018	
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69238-1422-6	1 in 1 CARTON	10/23/2018	
4		160 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209726	10/23/2018	

Labeler - Amneal Pharmaceuticals NY LLC (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals Private Limited		650762060	analysis(69238-1422) , label(69238-1422) , manufacture(69238-1422) , pack(69238-1422)

Revised: 12/2023 Amneal Pharmaceuticals NY LLC