DIPHENHYDRAMINE HCL AND IBUPROFEN - diphenhydramine hcl and ibuprofen capsule, liquid filled
Aurohealth LLC

Diphenhydramine HCL and Ibuprofen Capsules USP 25 mg/200 mg

Drug Facts

Active ingredients
(in each capsule)

Diphenhydramine hydrochloride USP 25 mg
Solubilized ibuprofen equal to 200 mg ibuprofen USP (NSAID)*
(present as the free acid and potassium salt)
*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: Ibuprofen 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 continuing medical illness
- taking any other antihistamines
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- 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

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use ibuprofen 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. [1-800-222-1222]

Directions

- **do not take more than directed**
- adults and children 12 years and over: take 2 capsules at bedtime
- do not take more than 2 capsules in 24 hours

Other information

- **each capsule contains:** potassium 20 mg
- read all warnings and directions before use. Keep carton.
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light
- Organic Impurities Test is Pending
- Meets USP dissolution test 2

Inactive ingredients

D&C Red No.33, gelatin, Neelicert FD&C Blue No.1, polyethylene glycol, potassium hydroxide, povidone, purified water, sorbitol sorbitan solution.

Questions or comments?

Call **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

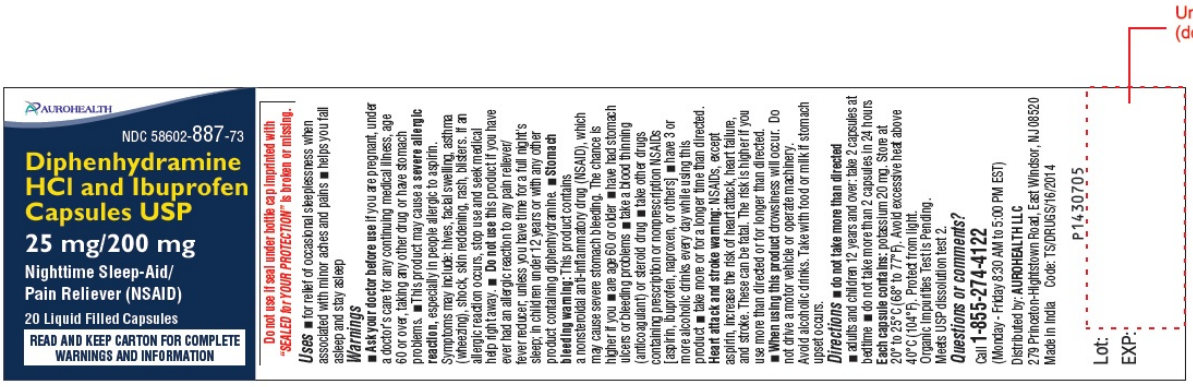
Distributed by:
AUROHEALTH LLC
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/16/2014

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 25 mg/200 mg (20 Liquid-Filled Capsules) Bottle Label

AUROHEALTH
NDC 58602-887-73
Diphenhydramine
HCl and Ibuprofen
Capsules USP
25 mg/200 mg
Nighttime Sleep-Aid/
Pain Reliever (NSAID)
20 Liquid Filled Capsules
READ AND KEEP CARTON FOR COMPLETE
WARNINGS AND INFORMATION



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 25 mg/200 mg (20 Liquid-Filled Capsules) Bottle Carton Label

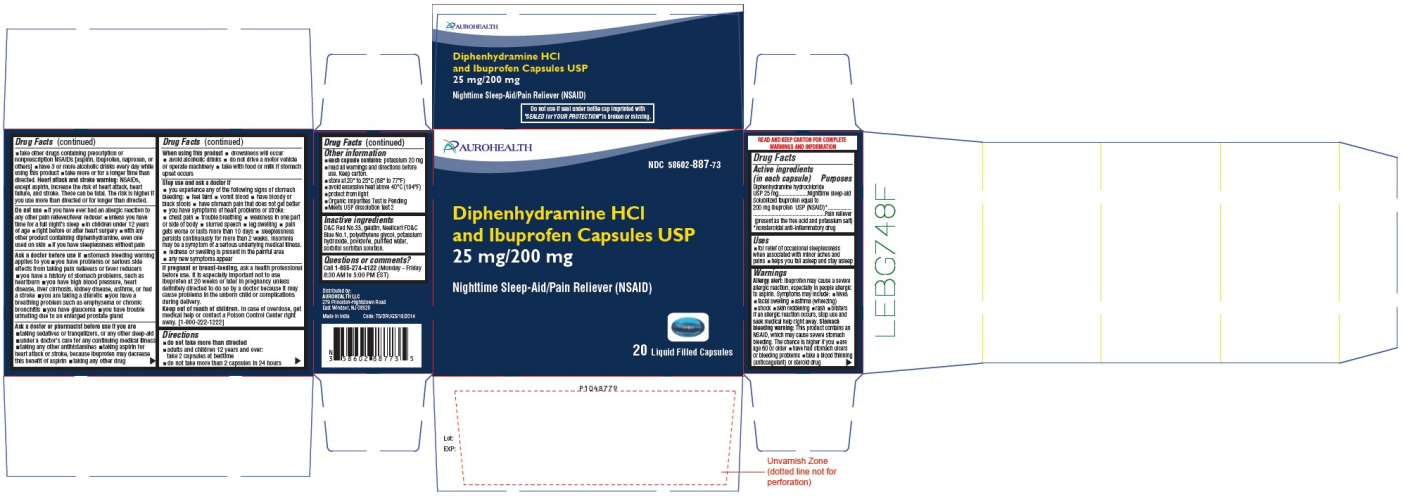
AUROHEALTH

NDC 58602-887-73

Diphenhydramine HCl
and Ibuprofen Capsules USP
25 mg/200 mg

Nighttime Sleep-Aid/Pain Reliever (NSAID)

20 Liquid Filled Capsules



DIPHENHYDRAMINE HCL AND IBUPROFEN

diphenhydramine hcl and ibuprofen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-887
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

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
1,4-SORBITAN (UNII: AV0YTZ4E6J)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
MANNITOL (UNII: 3OWL53L36A)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	DHI25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-887-73	1 in 1 CARTON	08/10/2022	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-887-10	1 in 1 CARTON	08/10/2022	
2		32 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-887-12	1 in 1 CARTON	08/10/2022	
3		40 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-887-18	1 in 1 CARTON	08/10/2022	
4		80 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-887-23	120 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2022	
6	NDC:58602-887-30	160 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA210676	08/10/2022	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-887) , MANUFACTURE(58602-887)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-887) , MANUFACTURE(58602-887)

Revised: 8/2022 Aurohealth LLC