IBUPROFEN AND DIPHENHYDRAMINE CITRATE - ibuprofen and diphenhydramine citrate tablet, coated
Aurohealth LLC

Diphenhydramine Citrate and Ibuprofen Tablets USP 38 mg/200 mg

Drug Facts

Active ingredients (in each caplet)

Diphenhydramine citrate USP 38 mg
Ibuprofen USP 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: 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 (1-800-222-1222) right away.

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

- 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)

Inactive ingredients

carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C blue # 2, glyceryl dibehenate, hypromellose, lactose monohydrate, microcrystalline cellulose,

palmitic acid, polydextrose, polyethylene glycol, pregelatinized starch (maize), sodium lauryl sulfate, sodium starch glycolate, stearic acid, and titanium dioxide.

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 No.: TS/DRUGS/16/2014

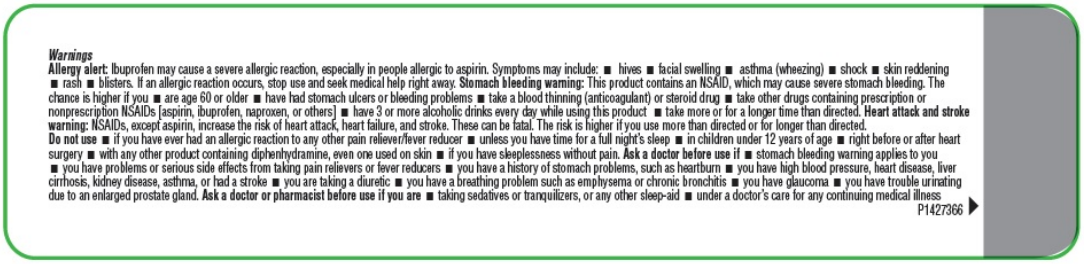
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg/38 mg (20 Coated Caplets) Bottle Label

AUROHEALTH
NDC 58602-867-73
Ibuprofen and
Diphenhydramine Citrate
Tablets
200 mg/38 mg
Pain Reliever (NSAID)/Nighttime Sleep-Aid
20
Coated Caplets* ***Capsule-Shaped Tablets**

Top Ply

Top Ply (Page #1)

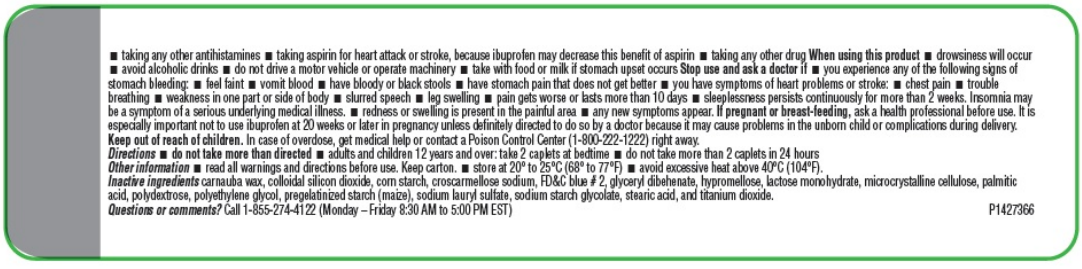
*Lot: XXXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be printed online during packing.



Back of Top Ply (Page #2)

Bottom Ply

Base (Page #3)

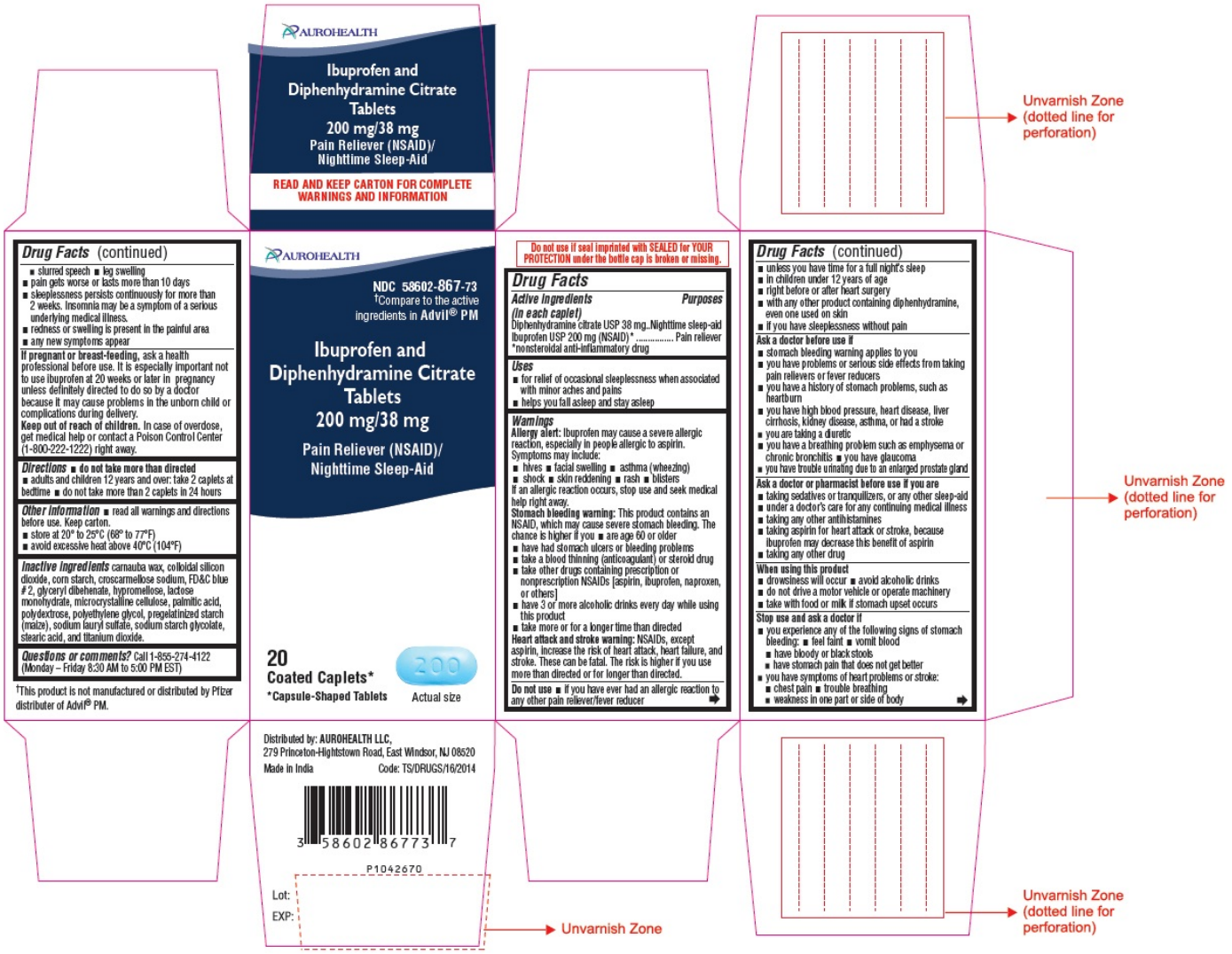


PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg/38 mg (20 Coated

Caplets) Bottle Carton Label

AUROHEALTH
NDC 58602-867-73
†Compare to the active ingredients in Advil® PM
Ibuprofen and Diphenhydramine Citrate Tablets
200 mg/38 mg
Pain Reliever (NSAID)/ Nighttime Sleep-Aid
20
Coated Caplets*
***Capsule-Shaped Tablets** **200**

Actual size



IBUPROFEN AND DIPHENHYDRAMINE CITRATE

ibuprofen and diphenhydramine citrate tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-867
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
DIPHENHYDRAMINE CITRATE (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
PALMITIC ACID (UNII: 2V16EO95H1)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	15mm
Flavor		**Imprint Code**	DI;200
Contains			

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-867-73	1 in 1 CARTON	05/31/2022	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-867-09	1 in 1 CARTON	05/31/2022	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-867-12	1 in 1 CARTON	05/31/2022	
3		40 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-867-14	1 in 1 CARTON	05/31/2022	
4		50 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-867-18	1 in 1 CARTON	05/31/2022	
5		80 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-867-21	1 in 1 CARTON	05/31/2022	
6		100 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:58602-867-23	1 in 1 CARTON	05/31/2022	
7		120 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:58602-867-27	140 in 1 BOTTLE; Type 0: Not a Combination Product	05/31/2022	
9	NDC:58602-867-32	180 in 1 BOTTLE; Type 0: Not a Combination Product	05/31/2022	
10	NDC:58602-867-34	200 in 1 BOTTLE; Type 0: Not a Combination Product	05/31/2022	
11	NDC:58602-867-70	1 in 1 CARTON	05/31/2022	
11		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
12	NDC:58602-867-78	1 in 1 CARTON	05/31/2022	
12		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
13	NDC:58602-867-72	1 in 1 CARTON	05/31/2022	
13		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
14	NDC:58602-867-97	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2022	
15	NDC:58602-867-46	140 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2022	
16	NDC:58602-867-92	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2022	
17	NDC:58602-867-80	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/31/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216204	05/31/2022	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-867) , MANUFACTURE(58602-867)

Revised: 6/2022 Aurohealth LLC