

**IBUPROFEN AND DIPHENHYDRAMINE CITRATE - ibuprofen and  
diphenhydramine citrate tablet, coated**  
**Better Living Brands, LLC**

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**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 caplets at bedtime
- do not take more than 2 caplets 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:**

BETTER LIVING BRANDS LLC  
P.O.BOX 99, PLEASANTON  
CA 94566-0009  
†1-888-723-3929

Made in India

Code: TS/DRUGS/16/2014

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

NDC 21130-228-73

**Signature**

**care®**

Quality

Guaranteed

**IBUPROFEN AND  
DIPHENHYDRAMINE CITRATE  
TABLETS 200 mg/38 mg**

**Pain Reliever (NSAID)/  
Nighttime Sleep-Aid**

**20 Coated Caplets\*\***

**\*\*Capsule-Shaped Tablets**

# Top Ply

		NDC 2130-228-73	
<b>IBUPROFEN AND DIPHENHYDRAMINE CITRATE TABLETS 200 mg/38 mg</b> Pain Reliever (NSAID)/ Nighttime Sleep-Aid 20 Coated Capslets** **Capsule-Shaped Tablets		<b>READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION</b> Do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.	<b>Active ingredients (in each caplet)</b> Diphenhydramine citrate USP 38 mg Ibuprofen USP 200 mg (NSAID)* *nonsteroidal anti-inflammatory drug <b>Purposes</b> Nighttime sleep-aid Pain reliever LM-5378 P1433051 No Varnish
DISTRIBUTED BY: BETTER LIVING BRANDS LLC P.O. BOX 99, PLEASANTON, CA 94566-0099 1-888-723-3929 RD 23153 S6289		 Made in India Code: TS/DRUGS/16/2014	

## Top Ply (Page #1)

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

<b>Warnings</b> 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 you have 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.	<b>HINGE</b>
LM-5378 P1433051	

## Back of Top Ply (Page #2)

# Bottom Ply

## Base (Page #3)

<b>HINGE</b>	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 caplets at bedtime, do not take more than 2 caplets 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: camellia 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).
	LM-5378 P1433051

## Caplets) Bottle Carton Label

Compare to Advil® PM  
active ingredients †

## Signature

care®

Quality

Guaranteed

NDC 21130-228-73

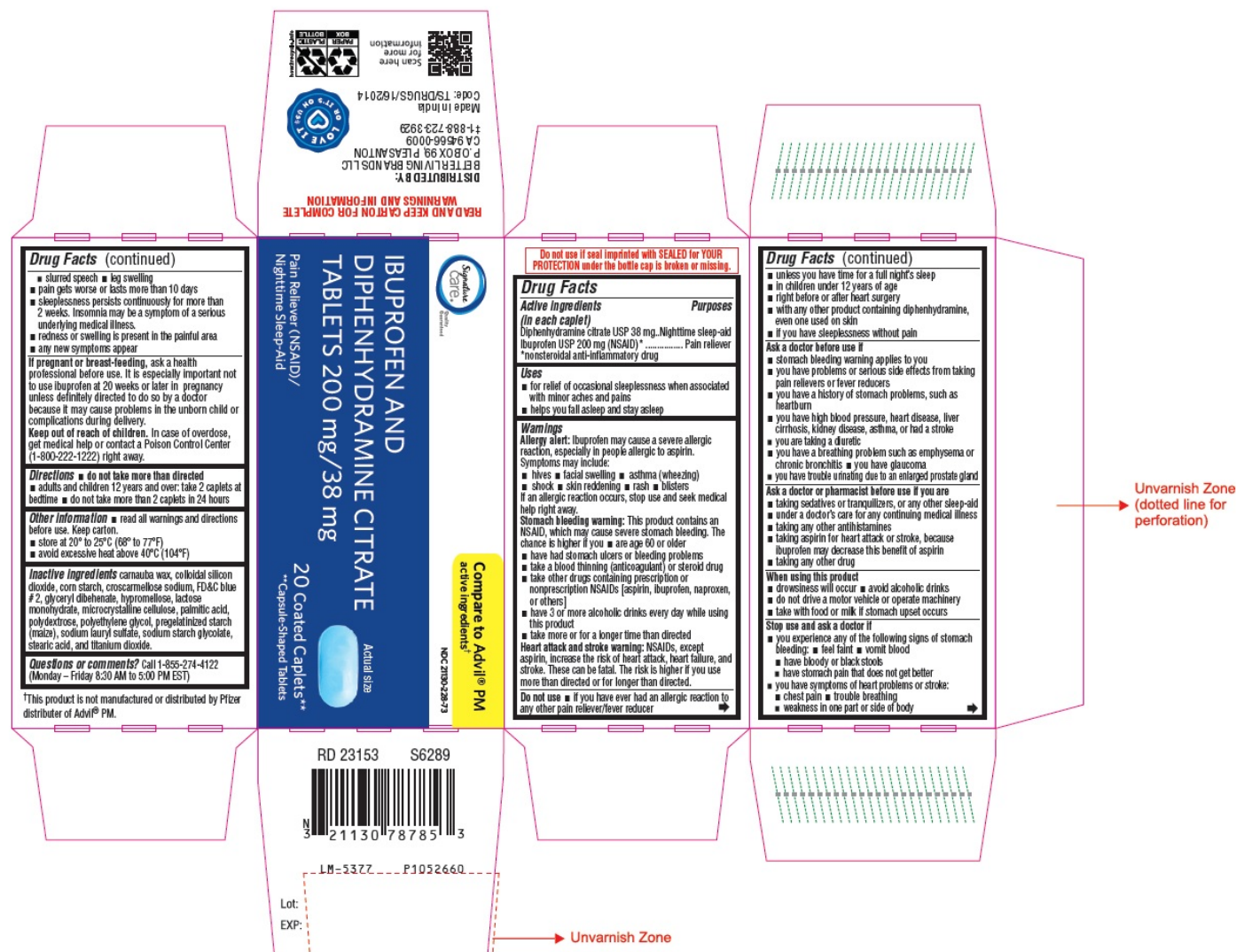
## IBUPROFEN AND DIPHENHYDRAMINE CITRATE TABLETS 200 mg/38 mg

Actual size

Pain Reliever (NSAID)/  
Nighttime Sleep-Aid

20 Coated Caplets\*\*

\*\*Capsule-Shaped Tablets



# IBUPROFEN AND DIPHENHYDRAMINE CITRATE

ibuprofen and diphenhydramine citrate tablet, coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-228
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Product Characteristics

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-228-73	1 in 1 CARTON	11/15/2023	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:21130-228-12	1 in 1 CARTON	11/15/2023	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:21130-228-18	1 in 1 CARTON	11/15/2023	
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:21130-228-23	1 in 1 CARTON	11/15/2023	
4		120 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		ANDA216204	11/15/2023	

**Labeler -** Better Living Brands, LLC (009137209)

**Registrant -** Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(21130-228) , MANUFACTURE(21130-228)

Revised: 11/2023

Better Living Brands, LLC