

**AMAZON BASIC CARE IBUPROFEN PM - ibuprofen and diphenhydramine
citrate tablet, coated
Amazon.com Services 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 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:

AMAZON.COM SERVICES LLC
410 TERRY AVENUE N., SEATTLE, WA 98109

Made in India

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg/38 mg (120 Coated Caplets) Bottle Label

amazon
basic+care

For Aches & Pains NDC 72288-061-77

**Ibuprofen PM
Ibuprofen and Diphenhydramine Citrate
Tablets, 200 mg/38 mg**

Pain Reliever (NSAID)/Nighttime Sleep-Aid

120 COATED CAPLETS**

****Capsule-Shaped Tablets**

Top Layer Printing side



basic+care

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Tablets, 200 mg/38 mg
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**Capsule-Shaped Tablets

Lift Here for Drug Facts 

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Do not use if seal imprinted with **SEALED** for YOUR PROTECTION under the bottle cap is broken or missing.

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410 TERRY AVENUE N.
SEATTLE, WA 98109
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LM-5671 P1434049

* Unvarnished Zone
(dotted line not for printing)
42 x 17 mm

Made in India

GLUTEN FREE

Top Layer Adhesive side

Active ingredients (in each caplet)

Diphenhydramine citrate USP 38 mg..... Nighttime sleep-aid
Ibuprofen USP 200 mg (NSAID)* Pain reliever
*nonsteroidal anti-inflammatory drug

Uses

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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 ➔

Purposes

Gluing Area

LM-5671 P1434049

Base Layer

■ 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.

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PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg/38 mg (120 Coated Caplets) Bottle Carton Label

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For Aches & Pains

NDC 72288-061-77

Ibuprofen PM

**Ibuprofen and Diphenhydramine Citrate Tablets,
200 mg/38 mg**

Pain Reliever (NSAID)/Nighttime Sleep-Aid

120 COATED CAPLETS**

****Capsule-Shaped Tablets**

actual size

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)	
CROSCARMELOSE 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				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288-061-77	1 in 1 CARTON	05/15/2024	
1		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	05/15/2024	
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Labeler - Amazon.com Services LLC (128990418)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(72288-061) , MANUFACTURE(72288-061)

Revised: 5/2024

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