IBUPROFEN PM- diphenhydramine citrate, ibuprofen tablet, coated
WR Group, Inc.

Drug Facts

Active ingredient (in each caplet)

Diphenhydramine citrate 38 mg

ibuprofen 200 mg(NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

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

- the stomach bleeding warning applies to you
- you have problem 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, or 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 decease 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 problem or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body

    - slurred speech
    - leg swelling
- pain gets worse or last 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 childlren 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 between 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

carnauba wax, corn starch, croscarmellose sodium, FD&C blue #2, hypromellose, microcrystalline cellulose, polydestrose, polyethylene glycol 400, silicon dioxide, stearic acid, titanium dioxide

Questions or comments?

Principal Display Panel

†Compare to the active ingredients in Advil® PM

IbuprofenPM

Ibuprofen 200 mg

Pain reliever (NSAID)*

Diphenhydramine citrate 38 mg

Nighttime sleep-aid

Coated caplets**

(**Capsules-shaped tablets)

†This product is not manufactured or distributed by Haleon Group of Companies distributor Advil® PM

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY:

Product Packaging

NDC 69607-1970-1

*Compare to the active ingredients in Advil PM

Ibuprofen PM

Ibuprofen 200 mg
*Pain reliever **(NSAID)***
Diphenhydramine citrate 38 mg
Nighttime sleep-aid

*120 Coated caplets***
*(**Capsule-shaped tablets)*

Actual Size

Drug Facts

Active ingredients (in each caplet) — **Purposes**

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

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Inactive ingredients carnauba wax, corn starch, croscarmellose sodium, FD&C blue #2, hypromellose, microcrystalline cellulose, polydextrose, polyethylene glycol 400, silicon dioxide, stearic acid, titanium dioxide

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Distributed by: (Specific to customer's labeling guide. Must state either: manufacturer, packer, or distributor)

PLD-A516B FD069358

Lot No.:

Exp. Date:

KOLBE & SCHMITT Ibuprofen PM

IBUPROFEN PM

diphenhydramine citrate, ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69607-1970
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL (Oblong)	**Size**	15mm
Flavor		**Imprint Code**	PL72
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69607-1970-1	1 in 1 BOX	02/28/2025	
1		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211404	02/28/2025	

Labeler - WR Group, Inc. (089173699)

Revised: 1/2025 WR Group, Inc.