

# **IBUPROFEN PM- diphenhydramine citrate, ibuprofen tablet, coated** **Safeway, Inc.**

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**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 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 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 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 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 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, polydextrose, polyethylene glycol 400, silicon dioxide, stearic acid, titanium dioxide

### **Questions or comments?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

### **Principal Display Panel**

COMPARE TO Advil® PM active ingredients†

Ibuprofen **PM**

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

BETTER LIVING BRANDS LLC

P.O. BOX 99

PLEASANTON, CA 94566-0009

**Product Packaging**

Exp. Date:

Lot No.:



DISTRIBUTED BY:  
 HALEON PHARMACEUTICALS  
 1000 WILSON AVENUE  
 FLEMINGTON, NJ 08822-1000  
 TEL: 908-723-3829



3



4

Scan here for product information



S2801

PLB-AS18A F030847Z

RD23080

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**Active Ingredients (in each caplet)**  
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 Ibuprofen 200 mg (NSAID)\*.....Pain reliever  
 \*nonsteroidal anti-inflammatory drug

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**Drug Facts (continued)**

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**Drug Facts (continued)**

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 ■ slurred speech ■ leg swelling  
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**Drug Facts (continued)**

**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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**Signature care.**  
 Quality You Demand™

**COMPARE TO Advil® PM**  
 active ingredients\*

NDC 21130-056-80

**Ibuprofen PM**  
 Actual Size

IBUPROFEN 200 mg  
 Pain Reliever (NSAID)  
 Diphenhydramine Citrate 38 mg  
 Nighttime Sleep-Aid

80 COATED CAPLETS\*\*  
 (\*\*capsule-shaped tablets)

**SIGNATURE CARE Ibuprofen PM**

<b>IBUPROFEN PM</b> diphenhydramine citrate, ibuprofen tablet, coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21130-056
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	PL72
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:21130-056-40	1 in 1 BOX	03/01/2024	
1		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:21130-056-80	1 in 1 BOX	03/01/2024	
2		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA211404	03/01/2024	

**Labeler** - Safeway, Inc. (009137209)

