

BERKLEY AND JENSEN IBUPROFEN PM- diphenhydramine citrate, ibuprofen tablet, coated BJWC

BJWC Ibuprofen PM Drug Facts

Active ingredients (in each caplet)

Diphenhydramine citrate 38 mg

Ibuprofen 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 during the last 3 months of 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 right away. (1-800-222-1222)

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.**
- store at 20-25°C (68 -77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, FD&C blue no. 2 aluminum lake, glyceryl behenate, hydroxypropyl cellulose, iron oxide black, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments?

1-800-934-1204

Principal Display Panel

Compare to the active ingredients in Advil® PM

IBUPROFEN PM

IBUPROFEN AND DIPHENHYDRAMINE CITRATE TABLETS, 200mg / 38mg

PAIN RELIEVER (NSAID)

NIGHTTIME SLEEP-AID

DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

gf GLUTEN FREE
 200 COATED CAPLETS**
 **CAPSULE-SHAPED TABLETS
 SEE NEW WARNINGS

Drug Facts (continued)

- 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

Compare to the active ingredients in Advil® PM†

berkley jensen®

IBUPROFEN PM

IBUPROFEN AND
DIPHENHYDRAMINE CITRATE
TABLETS, 200mg / 38mg

**PAIN RELIEVER (NSAID)
NIGHTTIME SLEEP-AID**

DO NOT USE IF PRINTED FOIL UNDER
CAP IS BROKEN OR MISSING

**200
COATED CAPLETS**** **SEE NEW
WARNINGS**

**CAPSULE-SHAPED TABLETS

GLUTEN FREE
gf®

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

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

Manf. #07579098
 BJ #88567
 8867004618
 8

PEEL BACK HERE

05082 D3 F2

Drug Facts (continued)

- 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

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of 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 right away. (1-800-222-1222)

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. store at 20-25°C (68-77°F) avoid excessive heat above 40°C (104°F)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, FD&C blue no. 2 aluminum lake, glyceryl behenate, hydroxypropyl cellulose, iron oxide black, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments? 1-800-934-1204

†This product is not manufactured or distributed by Pfizer, distributor of Advil® PM.
 Distributed by: BJ's Wholesale Club
 25 Research Drive, Westborough, MA 01581

**ADHESIVE AREA
NO COPY**

BERKLEY AND JENSEN IBUPROFEN PM

diphenhydramine citrate, ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68391-050
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DIPHENHYDRAMINE CITRATE (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE CITRATE	38 mg	
IBUPROFEN (UNII: WK2XYI10 QM) (IBUPROFEN - UNII:WK2XYI10 QM)		IBUPROFEN	200 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)				
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)				
FERROSO FERRIC OXIDE (UNII: XM0M87F357)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	BLUE	Score	no score	
Shape	OVAL (tablet)	Size	15mm	
Flavor		Imprint Code	L050	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68391-050-48	1 in 1 CARTON	04/27/2009	
1		180 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68391-050-82	200 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2017	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA079113	04/27/2009	

Labeler - BJWC (159082692)