IBUPROFEN PM- diphenhydramine citrate, ibuprofen tablet, coated
Rite Aid Corporation

Rite Aid Corporation Ibuprofen PM 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

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, or asthma
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- 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. Keep carton.
- 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?

1-800-719-9260

Principal Display Panel

SEE NEW WARNINGS INFORMATION

Compare to the active ingredients of Advil® PM Caplets

ibuprofen PM

ibuprofen and diphenhydramine citrate tablets, 200 mg/38 mg

pain reliever (NSAID)/ nighttime sleep-aid

actual size

20 CAPLETS†

†capsule-shaped tablets

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

RA# 0353685

0 11822 53685 1

LOT NO.

EXP.

**This product is not manufactured or distributed by Wyeth Consumer Healthcare, distributor of Advil® PM Caplets.

RITE AID PHARMACY

SEE NEW WARNINGS INFORMATION

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READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION.

DISTRIBUTED BY: RITE AID
30 HUNTER LANE, CAMP HILL, PA 17011

IF YOU'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.

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IBUPROFEN PM

diphenhydramine citrate, ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11822-0050
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: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	CAPSULE (tablet)	**Size**	15mm
Flavor		**Imprint Code**	L050
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11822-0050-1	1 in 1 CARTON		
1		80 in 1 BOTTLE		
2	NDC:11822-0050-2	1 in 1 CARTON		
2		40 in 1 BOTTLE		
3	NDC:11822-0050-3	1 in 1 CARTON		
3		20 in 1 BOTTLE		
4	NDC:11822-0050-4	1 in 1 CARTON		

4		30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079113	03/19/2009	

Labeler - Rite Aid Corporation (014578892)

Revised: 8/2013 Rite Aid Corporation