

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

Rite Aid Corporation 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 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 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

FREE FROM | GLUTEN FREE

Compare to the active ingredients of Advil® PM

IBUPROFEN PM

IBUPROFEN AND DIPHENHYDRAMINE CITRATE TABLETS, 200 mg/38 mg

PAIN RELIEVER (NSAID)/NIGHTTIME SLEEP-AID

ACTUAL SIZE

120 COATED CAPLETS**

**CAPSULE-SHAPED TABLETS

05076 83 CI


FREE
 FROM
GLUTEN
FREE

NDC 11822-0050-5

Compare to the active ingredients of Advil® PM***

IBUPROFEN PM

IBUPROFEN AND DIPHENHYDRAMINE
CITRATE TABLETS, 200 mg/38 mg
PAIN RELIEVER
(NSAID)/NIGHTTIME
SLEEP-AID

ACTUAL SIZE

120
COATED CAPLETS**

**CAPSULE-SHAPED TABLETS

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

 RITE AID
 200 NEUBERRY COMMONS
 ETTERS, PA 17319
 www.riteaid.com

SATISFACTION
GUARANTEE

 If you're not satisfied, we'll
 happily refund your money.

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

 READ AND KEEP CARTON FOR COMPLETE WARNINGS
 AND INFORMATION

Drug Facts
Active ingredients
(in each caplet)

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

Purposes
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.

Drug Facts (continued)
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

Drug Facts (continued)
■ 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 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

IBUPROFEN PM

diphenhydramine citrate, ibuprofen tablet, film 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: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FERROSFERRIC 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	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	06/24/2009	
1		80 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:11822-0050-2	1 in 1 CARTON	03/19/2009	08/23/2018
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:11822-0050-3	1 in 1 CARTON	03/19/2009	
3		20 in 1 BOTTLE; Type 0: Not a Combination		

3		Product		
4	NDC:11822-0050-4	1 in 1 CARTON	05/14/2009	11/20/2017
4		30 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:11822-0050-5	1 in 1 CARTON	08/23/2023	
5		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	ANDA079113	03/19/2009	

Labeler - Rite Aid Corporation (014578892)

Revised: 9/2023

Rite Aid Corporation