

EQUALINE IBUPROFEN PM- diphenhydramine citrate, ibuprofen tablet, coated **Supervalu Inc**

SuperValu Inc. 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

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, glyceryl behenate, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments?

1-877-932-7948

Principal Display Panel

compare to Motrin® PM active ingredients

ibuprofen PM caplets**

ibuprofen and diphenhydramine citrate tablets 200mg/38mg

pain reliever (NSAID)/nighttime sleep-aid

SEE NEW WARNINGS INFORMATION

20 coated caplets**

**capsule-shaped tablets

actual size

Drug Facts (continued)

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compare to Motrin[®] PM
active ingredients***
NDC 41163-561-60

EQUALINE[®]

ibuprofen PM caplets**

ibuprofen and diphenhydramine citrate tablets,
200mg/38mg

pain reliever (NSAID)/nighttime sleep-aid

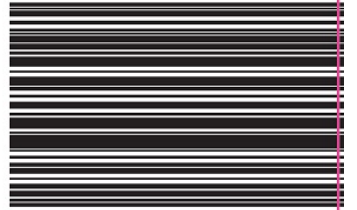
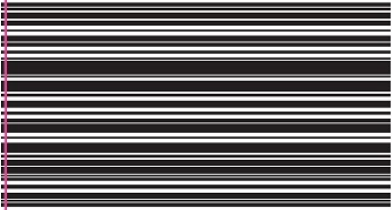
SEE NEW WARNINGS INFORMATION

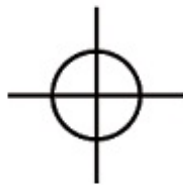
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actual size





EXP. DATE :

EXP.

LOT NO.



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

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Diphenhydramine citrate 38 mg.....	Nighttime sleep-aid
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Drug Facts
 Inactive ingredients
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acts (continued)

Ingredients colloidal silicon dioxide, xelose sodium, glyceryl behenate, xopol cellulose, lactose monohydrate, um stearate, microcrystalline cellulose, ene glycol, polyvinyl alcohol, pregelatinized ilc, titanium dioxide

Questions or comments? 1-877-932-7948

DO NOT OPEN AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION.

GLUTEN FREE

Product is not manufactured or distributed by McKel Consumer Healthcare, distributor of Motrin® PM.
Distributed by SUPERVALU INC.
10000 Prairie, MN 55344 USA
Contact us at 1-877-932-7948, or
www.supervalu-owned-brands.com

EQUALINE IBUPROFEN PM

diphenhydramine citrate, ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-561
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)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	15mm

Flavor		Imprint Code	L413
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-561-60	1 in 1 CARTON		
1		20 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079113	01/11/2012	

Labeler - Supervalu Inc (006961411)

Revised: 11/2014

Supervalu Inc