EQUALINE IBUPROFEN PM- diphenhydramine citrate and 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

ibuprofen and diphenhydramine citrate tablets, 200mg/38 mg

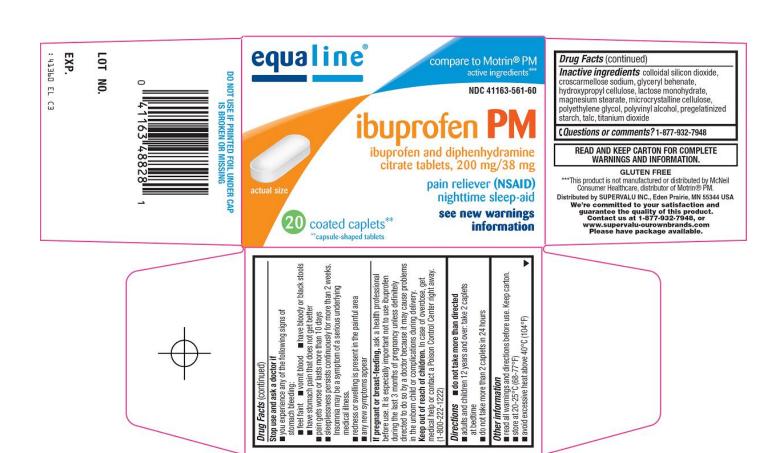
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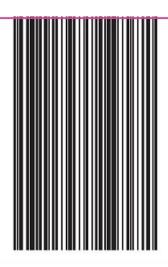
pain reliever (NSAID)

nighttime sleep-aid

see new warnings information

**capsule-shaped tablets





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Drug Facts (continued)

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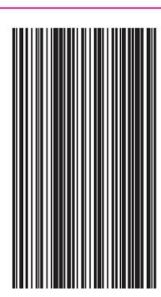
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EQUALINE IBUPROFEN PM

diphenhydramine citrate, ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41163-561
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE CITRATE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE CITRATE	38 mg	
IBUPRO FEN (IBUPRO FEN)	IBUPROFEN	200 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE		
CROSCARMELLOSE SODIUM		
GLYCERYL DIBEHENATE		
HYDROXYPROPYL CELLULOSE		
LACTOSE MONOHYDRATE		
MAGNESIUM STEARATE		
CELLULOSE, MICRO CRYSTALLINE		
POLYETHYLENE GLYCOLS		
POLYVINYL ALCOHOL		
TALC		
TITANIUM DIO XIDE		

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				
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

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Labeler - Supervalu Inc (006961411)

Revised: 9/2012 Supervalu Inc