

IBUPROFEN PM- ibuprofen and diphenhydramine hcl capsule, liquid filled
Valu Merchandisers Company (Best Choice)

Ibuprofen and Diphenhydramine HCl Softgels

Active Ingredients (in each capsule)

Diphenhydramine hydrochloride 25 mg

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*
(present as the free acid and potassium salt)

*non-steroidal 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:

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- take other drugs containing prescription or nonprescription NSAIDS [aspirin, ibuprofen, naproxin, or others]
- take more or for a longer time than directed.
- have 3 or more alcoholic drinks every day while using this product

Do not use

- in children under 12 years of age
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery
- unless you have time for a full night's sleep

- with any other product containing diphenhydramine , even one used on skin
- if you have sleeplessness without pain

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have glaucoma
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers.
- you have a breathing problem such as emphysema or chronic bronchitis
- 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
- taking any other drug
- taking any other antihistamines
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any continuing medical illness

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
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
 - pain gets worse or last 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

Directions

- **do not take more than directed**
- **adults and children 12 years and over:**
 - take 2 capsules at bedtime
 - do not take more than 2 capsules in 24 hours

Other information

- **each capsule contains:** potassium 20 mg
- read all warnings and directions before use. Keep carton.
- store at 20°-25°C (68°-77° F)
- avoid high humidity and excessively heat above 40° C (104° F)
- protect from light.

Inactive Ingredients

FD&C Blue #1, FD&C Red #40, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

Questions or comments?

call **1-877-753-3935 Monday- Friday 9AM-5PM EST**

Principal Display Panel

†Compare to the active ingredients in Advil® PM LIQUI-GELS®

IBUPROFEN PM SOFTGELS

Solubilized Ibuprofen, 200 mg

Diphenhydramine HCl, 25 mg

PAIN RELIEVER (NSAID)/ NIGHTTIME SLEEP-AID

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil® PM LIQUI-GELS®

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Product Label

Ibuprofen PM softgels

IBUPROFEN PM

ibuprofen and diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-166
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	BLUE (BLUE)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	IBUPM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-166-32	4 in 1 CARTON		
1		8 in 1 BLISTER PACK		
2	NDC:63941-166-16	2 in 1 CARTON		
2		8 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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ANDA	ANDA090397	06/10/2011	
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Labeler - Valu Merchandisers Company (Best Choice) (868703513)

Registrant - P and L Development of New York Corporation (800014821)

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Valu Merchandisers Company (Best Choice)