

**IBUPROFEN PM- ibuprofen, diphenhydramine hcl capsule, liquid filled
Dolgenercorp, Inc. (DOLLAR GENERAL & REXALL)**

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine hydrochloride USP 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:

- 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]
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

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 reliever or fever reducer
- 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
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- you have symptoms of heart problem or stroke:
 - chest pain
 - trouble breathing
 - leg swelling

- slurred speech
- weakness in one part or side of body
- 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 (1-800-222-1222) 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° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light
- Organic impurities Test is pending
- USP Dissolution Test is pending
- swallow whole; do not crush, chew, or dissolve

Inactive ingredients

D&C red #33, gelatin, hypromellose, isopropyl alcohol, Neelcert FD&C Blue No. 1, polyethylene glycol, propylene glycol, potassium hydroxide, povidone, purified water, sorbitan, sorbitol, titanium dioxide

Questions or comments?

Call **1-888-309-9030**

Principal Display Panel

Compare to the active ingredients of Advil® PM**

Ibuprofen PM Capsules

Ibuprofen 200 mg /

Pain reliever (NSAID)

Diphenhydramine HCl 25 mg /

Nighttime Sleep-Aid

SOFTGELS**

(**liquid filled capsules)

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

TAMPER-EVIDENT: Do not use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" IS broken or missing.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

Product Packaging

ORAL

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)			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)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
GELATIN (UNII: 2G86QN327L)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)				
WATER (UNII: 059QF0KO0R)				
SORBITAN (UNII: 6O92ICV9RU)				
SORBITOL (UNII: 506T60A25R)				
ALCOHOL (UNII: 3K9958V90M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
POVIDONE (UNII: FZ989GH94E)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	15mm	
Flavor		Imprint Code	DH125	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-125-20	1 in 1 BOX	02/29/2016	01/29/2025
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA210676		02/29/2016	01/29/2025

Labeler - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)

