IBUPROFEN PM- ibuprofen, diphenhydramine hcl capsule, liquid filled Dolgencorp, 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 thining (antocoagulant) 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. Tyhese 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 decease 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 childlren 12 years and over: take 2 capsules at bedtime
 o 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, Neelicert 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 f seal under bottle cap mprinted with "SEALED for YOUR ROTECTION" 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

	Drug Facts (continued) worse or lasts more than 10 days = sleeplessness persists continuously for more than 2 weeks, insommia mey be a symptom of a serious underlying medical illness. The medicate of a serious underlying medical illness. = any new symptoms appear = any new symptoms appear = any new symptoms appear during the last 3 months of pregnancy unless definitely defice use. It is sepatially important not to use buprotein during the last 3 months of pregnancy unless definitely deficers of the sub-back of the law curse problems in the unborn child or complications during delivery. Keep out of reach of children. In case of werchose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Denote the aution of take more than 2 capsulse a during and children 12 years and ower: take 2 capsulse at beditme a do not take more than 2 capsulse in 24 hours. Difrections a end al warnings and directions define use. Keep caton. — store at 20° to 35° (68° to 77°). — a avoid excessive heat above the 2 capsulse in 24 hours. Differ information — each capsulse and directions define use. Keep caton. — store at 20° to 35° (68° to 77°). — avoid excessive heat above the of 0° c (10.4°°). They Dissolution Take is pending . USP Dissolution Take is pending — swallow whole; do not curst, they or ophytene glycol, protasistum hydroxide, powdore. Hours, indenoval.	Call 1-888-309-9030
A0195 3 5 9 7 2 6 1 6 5 2 2 8 FC007/01 Lot No: Exp. Date:	Drug Facts (continued) Do not use if you have ever had an allergic reaction to any other pain relivewriter reducer Do not the pain relivewritever reducer aury status ever had an allergic reaction to any other product containing diphetime reducer Do not ker pain relivewritever reducer autiess you have stepplessons without pain on skin Di not aking pain relivewritever reducer autiess you have stepplessons without pain on skin Fact a forth and the problems or sensus side effects from taking pain relevers or feren cellocers you have high blood pressure, heart disease, hearthum Pay our have high blood pressure, heart disease, invectively and the problems such as emphysican an environ pain effects from taking and meters or feren exclusers You have a platrom you have broothing and meters or feren effects Drout are platrom you have taking admetic problems or a prosting pain to a stroke stroke stroke stroke stroke stroke stroke and prostile gland Ast a doctor potencies at you have trouble urinating due to a netating problem such as entroke the stroke	
	Drug Facts Purposes fin each capsulents Purposes fin each capsulents Purposes fin each capsulents Purposes Diphenhydramine hydrochorden Bydraware USP 25 mg. Diphenhydramine hydrochorden Solubilized lbuproten USP (XSUD)* Purposes Solubilized lbuproten USP (XSUD)* Pain reliever Solubilized lbuproten USP (XSUD)* Pain reliever Dipresent as the free acid and potassium salt) Pin reliever "torseerd as the free acid and potassium salt) Pin reliever "torseerd are the free acid and potassium salt) Pin reliever "torseerd are the free acid and potassium salt) Bin reliever "torseerd are and pains Bin reliever Marty alert. buprofen may cause a severe allergic traction cocurs sho use associated with more acids and stay asleep Bin and stay asleep Warnings Bisters. This product cortains an NSAUs Bisters. This product cortains an NSAUs who warming. This product cortains an Stay asleep and stay asleep or about the astorn diverse or others? Bisters. Bisters. Have 3 or more acids and or start directed. Heart Attack and throw and stay asleep or a bisters. This product cortains an NSAUs start directed. Heart Attack and throw and stas and forected. Heart Attack and throw and throbes	heart attack, heart failure, and stroke. These can be fatal. The fisk is higher if you use more than directed or for longer than directed.
	DG [™] health	
	Ibuprofen PM Capsules Ibuprofen 200 mg/ Pain reliever (NSAID) Diphenhydramine HCl 25 mg/ Nighttime sleep-aid	
	DOLLAR GENERAL HEALTH Ibuprofen	РМ
IBUPROFEN PM		

ibuprofen, diphenhydramine hcl capsule, liquid filled

DTC DRUG	ltem Code (Source)	NDC:55910-125

Active Ingred	ient/Activ	e Moiety					
	Ingredient Name			Basis of Strength		Strength	
IBUPROFEN (UNII:	WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)			IBUPROFEN		200 mg	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		TC2D6JAD40)	DIPHENHYDRAMINE HYDROCHLORIDE		25 mg		
Inactive Ingre	edients						
Ingredient Name						Strength	
FD&C BLUE NO. 1	L (UNII: H3R4	7K3TBD)					
D&C RED NO. 33	•	SBBOL)					
GELATIN (UNII: 2G							
POLYETHYLENE G			-				
POTASSIUM HYDE		: WZH3C48M4T)					
WATER (UNII: 0590							
SORBITAN (UNII: 6							
SORBITOL (UNII: 5 ALCOHOL (UNII: 3)							
PROPYLENE GLYC		C90167\/3)					
POVIDONE (UNII: F	-						
TITANIUM DIOXID							
HYPROMELLOSE,			9V3WO)				
Product Char	acteristic	S					
Color		blue Score		no score			
Shape		OVAL Size		15mm			
Flavor			Imprint Code		DH125)H125	
Contains							
Packaging							
# Item Code		Package De	scription	Marketing Sta Date		eting End Date	
1 NDC:55910- 125-20	1 in 1 BOX		02/29/2016	01/29/20	25		
	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product						
1							
1							
	Combination	Product					
1 Marketing Category	Combination	ation	er or Monograph	Marketing Star Date		eting End Date	

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