

IBUPROFEN PM- ibuprofen, diphenhydramine hcl capsule, liquid filled
CVS Pharmacy

Drug Facts

Active ingredient (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:

- 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

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

- the stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers 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
- under a doctor's care for any continuing medical illness
- 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 right away (1-800-222-1222).

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
- swallow whole; do not crush, chew or dissolve

Inactive ingredients

D&C red#33, FD&C blue #1 gelatin, medium chain triglycerides, polyethylene glycol 600, 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®†

Softgels**

Ibuprofen **PM**

IBUPROFEN, 200 mg

DIPHENHYDRAMINE HCl, 25 mg

Pain reliever (NSAID)

Nighttime sleep-aid

SOFTGELS**

**liquid filled capsules

†This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor Advil® PM LIQUI-GELS®.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

CVS.com 1-800-SHOP CVS

Product Packaging

Exp. Date:

Lot No.:

#213617



PLD-C531A FC005993

Actual Size

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
© 2019 CVS/Pharmacy
CVS.com® 1-800-SHOP CVS
V-16402

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*nonsteroidal anti-inflammatory drug

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Inactive ingredients andison, D&C red #33, FD&C blue #1, gelatin, hydrolyzed gelatin, medium chain triglycerides, croscodex white ink, polyethylene glycol 600, potassium hydroxide, purified water

Ingredients of croscodex white ink: shellac glaze in ethanol, titanium dioxide, n-butyl alcohol, lecithin (soy), simethicone, purified water

Questions or comments?

Call 1-877-733-3935 Monday-Friday, 9AM-5PM EST

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

Softgels**

NDC 69842-656-40

Ibuprofen PM

IBUPROFEN, 200 mg
DIPHENHYDRAMINE HCl, 25 mg

Pain reliever (NSAID)
Nighttime sleep-aid

40 SOFTGELS**
**Liquid-filled capsules



Actual Product Size on Side Panel



IBUPROFEN PM

ibuprofen, diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-656
Route of Administration	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)	

Product Characteristics

Color	purple (Bluish purple)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	1007
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-656-40	1 in 1 BOX	03/31/2019	03/31/2025
1		40 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	ANDA200888	03/31/2019	03/31/2025

Labeler - CVS Pharmacy (062312574)

Revised: 11/2022

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