

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

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**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:

- 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, 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**

- 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

### **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, FD&C blue #1, gelatin, hypromellose, isopropyl alcohol, polyethylene glycol, propylene glycol, potassium hydroxide, povidone, purified water, sorbitan, sorbitol, titanium dioxide

### **Questions or comments?**

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

### **Principal Display Panel**

Compare to the active ingredients in Advil® PM†

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.

**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.**

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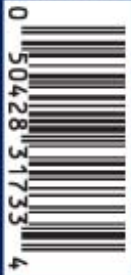
One CVS Drive, Woonsocket, RI 02895

CVS.com 1-800-SHOP CVS

**Product Packaging**

Exp. Date: \_\_\_\_\_  
Lot No.: \_\_\_\_\_

#213617



PLD-A690A F0007190

CVS Quality  
Member Since October 2015

Actual Size

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V-31884

**Drug Facts (continued)**

- sleepiness 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
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- 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 caplin.
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light
- USP Dissolution Test is pending
- USP Disintegration Test is pending
- swallow whole; do not crush, chew, or dissolve

**Inactive Ingredients** D&C Ink No. 33, gelatin, hydroxyethylcellulose, polyethylene glycol, polyethylene glycol, polyethylene glycol, polyethylene glycol, polyethylene glycol, polyethylene glycol, purified water, sorbitol sorbitol solution, titanium dioxide

**Questions or comments?**  
Call 1-877-755-3005 Monday-Friday 9AM-5PM EST

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**TAMPER EVIDENT: DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.**

**KEEP OUT OF REACH OF CHILDREN. READ COMPLETE WARNINGS AND PRODUCT INFORMATION.**

**Drug Facts (continued)**

- 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, vomiting, or diarrhea
- 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, 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 anticholinergics
- taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin
- taking any other drug

**When using this product**

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- avoid alcoholic drinks
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- take with food or milk if stomach upset occurs

**Stop use and ask a doctor if**

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- leg swelling
- slurred speech
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**Drug Facts**

**Active Ingredients**  
(in each capsule)  
Diphenhydramine hydrochloride USP 25 mg.....Nighttime sleep-aid  
200 mg Ibuprofen USP (NSAID).....Pain reliever  
(present as the free acid and potassium salt)  
Nonsteroidal anti-inflammatory drug

**Purposes**

- for relief of occasional sleeplessness when associated with minor aches and pains
- helps you fall asleep and stay asleep

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- unless you have time for a full night's sleep
- in children under 12 years of age
- right before or after heart surgery

**CVS Health.** Compare to the active ingredients in Advil® PM

**Softgels\*\***


NDC 69842-913-40

# 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

CVS HEALTH Ibuprofen PM Softgels

IBUPROFEN PM

ibuprofen, diphenhydramine hcl capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-913
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	DHI25
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-913-40	1 in 1 BOX	05/29/2020	
1		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA210676	05/29/2020	

**Labeler** - CVS Pharmacy (062312574)

Revised: 11/2022

CVS Pharmacy