

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

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**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:

- 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

**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
- 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.

**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 high humidity and excessive heat above 40°C (104°F)
- protect from light
- do not chew, crush, or dissolve capsule before swallowing

**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**

**SEE NEW WARNINGS**

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

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®.

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.  
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

CVS.com 1-800-SHOP CVS

**Product Packaging**

Lot No.:  
Exp. Date:

#213617



P.L.D. 81126 F0004562 Rev# 08/17

**CVS Quality**  
Money Back Guarantee

Actual Size

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CVS.com® 1-800-SHOP CVS  
V-16402

**Drug Facts**

**Active ingredients (in each capsule)** **Purposes**  
Diphenhydramine hydrochloride 25 mg.....Nighttime sleep-aid  
Solisibed ibuprofen equal to  
200 mg ibuprofen (NSAID)\*.....Pain reliever  
(present as the free acid and potassium salt)  
\*nonsteroidal anti-inflammatory drug

**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  
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■ 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**  
■ 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

**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**  
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■ you have glaucoma  
■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke  
■ you are taking a diuretic  
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■ you have a breathing problem such as emphysema or chronic bronchitis  
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■ you have symptoms of heart problems or stroke:  
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■ leg swelling ■ slurred speech  
■ weakness in one part or side of body  
■ pain gets worse or lasts more than 10 days

**Drug Facts (continued)**

■ 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  
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■ take 2 capsules at bedtime  
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■ each capsule contains: potassium 20 mg  
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■ read all warnings and directions before use. Keep carton.  
■ do not chew, crush, or dissolve capsule before swallowing

**Inactive ingredients** FD&C blue #1, FD&C red #40, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol, sorbitol

**Questions or comments?**  
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This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Advil® PM Liqui-Gels®.

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CVS Health.

Compare to the active ingredients in Advil® PM Liqui-Gels®†

Softgels\*\*

SEE NEW WARNINGS

NDC 69842-165-40

**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:69842-165
<b>Route of Administration</b>	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: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

**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>	IBUPM
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-165-40	1 in 1 BOX	09/30/2016	12/31/2020
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
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ANDA	ANDA090397	09/30/2016	12/31/2020
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**Labeler** - CVS Pharmacy (062312574)

Revised: 10/2019

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