

**IBUPROFEN PM- ibuprofen, diphenhydramine hcl capsule, liquid filled  
TOP CARE (Topco Associates LLC)**

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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

**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
- 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, asthma or had a stroke
- 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 problems 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
- 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
- read all warnings and directions before use. Keep carton.

**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 toll free **1-888-423-0139**

**Principal Display Panel**

COMPARE TO ADVIL® PM LIQUI-GELS® ACTIVE INGREDIENTS†

NIGHTTIME

Ibuprofen PM Capsules

PAIN RELIEVER (NSAID) • NIGHTTIME SLEEP-AID

IBUPROFEN & DIPHENHYDRAMINE HCl 200 mg/25mg

**SOFTGELS\*\***

\*\*Liquid-Filled Capsules

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

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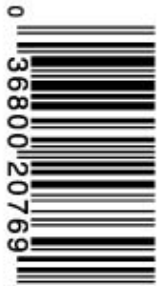
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www.topcarebrand.com

**Product Packaging**

Exp. Date:  
Lot No.:



PLD-A531A FC050608



This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

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NDC 36800-756-40

**TopCare**  
health™

**NIGHTTIME**

**Ibuprofen PM**

**Capsules PAIN RELIEVER (NSAID) • NIGHTTIME SLEEP-AID**  
IBUPROFEN & DIPHENHYDRAMINE HCl, 200 mg/25 mg

**40 SOFTGELS\*\***  
\*\*Liquid-Filled Capsules

actual size



COMPARE TO  
ADVIL® PM LIQUI-GELS®  
ACTIVE INGREDIENTS†

### Drug Facts

#### Active ingredients (in each capsule) Purposes

Diphenhydramine hydrochloride 25 mg.....Nighttime sleep-aid  
Sulbuzolid 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:  
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■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)  
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- 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

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  - you have a history of stomach problems, such as heartburn
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  - 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
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- taking sedatives or tranquilizers, or any other sleep-aid
  - taking any other drug
  - 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 anti-inflammatories

#### When using this product

- drowsiness will occur
- avoid alcoholic drinks
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#### Stop use and ask a doctor if

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■ feel faint  
■ vomit blood
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:  
■ chest pain ■ trouble breathing  
■ 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

■ any new symptoms appear

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- avoid excessive heat above 40°C (104°F) ■ protect from light
- swallow whole; do not crush, chew, or dissolve
- read all warnings and directions before use. Keep carton.

**Inactive ingredients** anidrisorb, D&C red #33, FD&C blue #1, gelatin, hydroxyzed gelatin, medium chain triglycerides, opacode white ink, polyethylene glycol 800, potassium hydroxide, purified water  
Ingredients of opacode white ink: shellac, glass, in ethanol, titanium dioxide, n-butyl alcohol, lecithin (soy), simethicone, purified water

#### Questions or comments? Call toll free 1-888-423-0139

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# TOPCARE Ibuprofen 200 mg Softgels

## IBUPROFEN PM

ibuprofen, diphenhydramine hcl capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-756
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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

Ingredient Name	Strength
<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 600</b> (UNII: NL4J9F21N9)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	1007
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-756-40	1 in 1 BOX	07/31/2018	
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	07/31/2018	

**Labeler** - TOP CARE (Topco Associates LLC) (006935977)

Revised: 11/2022

TOP CARE (Topco Associates LLC)