

**SMART SENSE IBUPROFEN PM- diphenhydramine citrate, ibuprofen tablet, coated**  
**Kmart Corporation**

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**Kmart Corporation Ibuprofen PM Drug Facts**

**Active ingredients (in each caplet)**

Diphenhydramine citrate 38 mg

Ibuprofen 200 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purposes**

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

**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 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, or asthma
- 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
- 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
- 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
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts 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 caplets at bedtime
- do not take more than 2 caplets in 24 hours

**Other information**

- read all warnings and directions before use. Keep carton.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

**Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, FD&C blue no. 2 aluminum lake, glyceryl behenate, hydroxypropyl cellulose, iron oxide black, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

**Questions or comments?**

1-800-719-9260

**Principal Display Panel**

COMPARE TO ACTIVE INGREDIENTS IN ADVIL® PM CAPLETS

Ibuprofen PM

Ibuprofen and Diphenhydramine Citrate Tablets, 200 mg/38 mg

ACTUAL SIZE

PAIN RELIEVER (NSAID) / NIGHTTIME SLEEP-AID

COATED CAPLETS\*\*

20 CAPLETS\*\*

\*\*CAPSULE-SHAPED TABLETS

LOT NO.  
EXP.  
: 05060 FT CS

**smart sense**

# Ibuprofen PM

Ibuprofen and Diphenhydramine Citrate Tablets, 200 mg/38 mg

PAIN RELIEVER (NSAID) / NIGHTTIME SLEEP-AID

NDC 49738-191-60  
COMPARE TO ACTIVE INGREDIENTS IN  
ADVIL® PM CAPLETS\*\*\*

ACTUAL SIZE

COATED CAPLETS\*\*

20 CAPLETS\*\*

\*\*\*CAPSULE-SHAPED TABLETS

**Drug Facts (continued)**

**Inactive ingredients** colloidal silicon dioxide, croscarmellose sodium, FD&C blue no. 2 aluminum lake, glyceryl behenate, hydroxypropyl cellulose, iron oxide black, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

**Questions or comments? 1-800-719-9260**

**READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION.**

\*\*\*This product is not manufactured or distributed by Wyeth Consumer Healthcare, distributor of Advil® PM Caplets.

Distributed by: Kmart Corporation  
Hoffman Estates, IL 60179  
[Shop.kmart.com](http://Shop.kmart.com)

If you are unsatisfied for any reason, return the unused portion to the store for a full refund or call 1-800-842-7886.

GLUTEN FREE

**Drug Facts (continued)**

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Insomnia may be a symptom of a serious underlying medical illness.

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Ibuprofen 200 mg (NSAID).....	Pain reliever

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**Drug Facts (continued)**

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## SMART SENSE IBUPROFEN PM

diphenhydramine citrate, ibuprofen tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49738-191
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE CITRATE (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

**Inactive Ingredients**

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OPIR32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

**Product Characteristics**

Color	BLUE	Score	no score
Shape	CAPSULE (tablet)	Size	15mm
Flavor		Imprint Code	L050
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49738-191-60	1 in 1 CARTON	06/04/2010	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49738-191-27	1 in 1 CARTON	05/27/2010	
2		80 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:49738-191-76	1 in 1 CARTON	04/29/2017	
3		120 in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079113	05/27/2010	

