

# **CARE ONE IBUPROFEN PM- diphenhydramine citrate and ibuprofen tablet, film coated**

**American Sales Company**

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## **American Sales Company 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

**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**

- 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, 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
- 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
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better

- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- 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 at 20 weeks or later in 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 the 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**

CAREone®

Compare to the active ingredients in Advil® PM Caplets

IBUPROFEN PM

Ibuprofen 200 mg/Diphenhydramine Citrate 38 mg Tablets

Pain Reliever (NSAID)/Nighttime Sleep-Aid

Actual Size

Gluten Free

120 CAPLETS\*\*

\*\*Capsule-Shaped Tablets



CARE ONE IBUPROFEN PM			
diphenhydramine citrate and ibuprofen tablet, film coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-050
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE CITRATE</b> (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg
<b>IBUPROFEN</b> (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>GLYCERYL DIBEHENATE</b> (UNII: R8WTH25YS2)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<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>	L050
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-050-27	1 in 1 CARTON	02/20/2009	
1		80 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41520-050-48	1 in 1 CARTON	03/06/2009	12/30/2018
2		180 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41520-050-58	1 in 1 CARTON	02/20/2009	
3		40 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:41520-050-60	1 in 1 CARTON	02/20/2009	
4		20 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:41520-050-82	200 in 1 BOTTLE; Type 0: Not a Combination Product	09/05/2017	
6	NDC:41520-050-76	1 in 1 CARTON	02/08/2018	

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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	02/20/2009	

**Labeler** - American Sales Company (809183973)

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American Sales Company