

**HARRIS TEETER IBUPROFEN PM- diphenhydramine citrate, ibuprofen tablet, film coated**  
**Harris Teeter, LLC**

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**Harris Teeter, LLC 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 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**

Ibuprofen PM

Compare to the active ingredients in Advil® PM

Ibuprofen and Diphenhydramine Citrate Tablets, 200 mg/38 mg

PAIN RELIEVER (NSAID)/NIGHTTIME SLEEP-AID

See New Warnings

80 COATED CAPLETS\*\*

\*\*Capsule-Shaped Tablets

Actual Size



05027 HT C2



0 72036 71457 2

<p style="text-align: center;"><b>READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION</b></p> <p><b>Drug Facts</b> (In each caplet)</p> <p><b>Active Ingredients</b>      <b>Purposes</b> Diphenhydramine citrate 38 mg... Nighttime sleep-aid Ibuprofen 200 mg (NSAID)*..... Pain reliever *nonsteroidal anti-inflammatory drug</p> <p><b>Uses</b>    ■ for relief of occasional sleeplessness when associated with minor aches and pains    ■ helps you fall asleep and stay asleep</p> <p><b>Warnings</b> 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. The risk is higher if you use more than directed or for longer than directed.</p>	<p><b>Drug Facts (continued)</b></p> <p>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</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p>	<p><b>Drug Facts (continued)</b></p> <p>■ dazed speech    ■ leg swelling    ■ pain gets worse or lasts more than 10 days    ■ sleeplessness persists continuously for more than 2 weeks. In some cases, sleeplessness may be a symptom of a serious underlying medical illness. ■ redness or swelling is present in the painful area ■ any new symptoms appear</p> <p>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).</p> <p><b>Directions</b>    ■ 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</p> <p><b>Other information</b>    ■ 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)</p> <p><b>Inactive ingredients</b> colloidal silicon dioxide, croscarmellose sodium, FD&amp;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</p> <p><b>Questions or comments?</b> 1-800-719-9260</p>
<p style="text-align: right;"><b>DON'T USE IPRUFROFEN UNDER CAP IS BROKEN OR MISSING</b></p> <p style="text-align: center;">This product is not manufactured or distributed by Pfizer, its subsidiary or Advil® PM.</p> <p style="text-align: center;"><b>your plus guarantee.</b></p> <p style="text-align: center;">If you are not 100% satisfied with this product, simply return it with this card for a full refund. Please call 1-800-719-9260 for the brand you're using. For full details: 1-800-422-6111 or <a href="http://www.refund.com">www.refund.com</a>.</p> <p style="text-align: center;">PRODUCED AND DISTRIBUTED BY: <b>HARRIS TEETER, LLC</b> MATT HENNS, NC 28016</p>		

# HARRIS TEETER IBUPROFEN PM

diphenhydramine citrate, ibuprofen tablet, film coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69256-050
Route of Administration	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)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	L050
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69256-050-27	1 in 1 CARTON	11/21/2015	
1		80 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69256-050-58	1 in 1 CARTON	11/21/2015	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69256-050-60	1 in 1 CARTON	11/05/2015	

3	20 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA079113	11/05/2015	

**Labeler** - Harris Teeter, LLC (048463103)

Revised: 12/2019

Harris Teeter, LLC