

**ADVIL PM- ibuprofen and diphenhydramine citrate tablet, coated**  
**Lil' Drug Store Products, Inc.**

-----  
**Advil® PM**

**Drug Facts**

<b>Active ingredient (in each caplet)</b>	<b>Purposes</b>
Diphenhydramine citrate 38 mg	Nighttime sleep-aid
Ibuprofen 200 mg (NSAID)*	Pain reliever

\* 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

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.

**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**

calcium stearate, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C blue no. 2 aluminum lake, glyceryl behenate, hypromellose, lactose monohydrate, microcrystalline cellulose, pharmaceutical ink, polydextrose, polyethylene glycol, pregelatinized starch, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

**Questions or comments?**

Call weekdays 9 AM to 5 PM EST at **1-800-88-ADVIL**

**Repackaged and distributed with permission of Pfizer Consumer Healthcare by:**  
Lil' Drug Store Products, Inc., 1201 Continental Place NE, Cedar Rapids, IA 52402

**PRINCIPAL DISPLAY PANEL - 4 COATED CAPLETS Carton****Advil® PM**

Ibuprofen, 200 mg / Diphenhydramine citrate, 38 mg  
Pain Reliever (**NSAID**) / Nighttime Sleep Aid

**Caplets****4****COATED  
CAPLETS\***

\*Capsule-Shaped Tablets

**Lil'  
Drug Store®**

# Advil<sup>®</sup> PM

Ibuprofen, 200 mg / Diphenhydramine citrate, 38 mg  
Pain Reliever (NSAID) / Nighttime Sleep-Aid



Caplets

4 COATED  
CAPLETS\*

\*Capsule-Shaped Tablets



Ibuprofen, 200 mg /  
Diphenhydramine citrate, 38 mg  
Pain Reliever (NSAID) /  
Nighttime Sleep-Aid

4 COATED  
CAPLETS\*  
Advil<sup>®</sup> PM

## READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

### Drug Facts

#### Active ingredients (in each caplet)

Diphenhydramine citrate 38 mg ..... Nighttime sleep-aid  
Ibuprofen 200 mg (NSAID) \* ..... Pain reliever  
\*nonsteroidal anti-inflammatory drug

#### Purposes

#### 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

LIFT HERE For More Drug Facts

Ibuprofen, 200 mg /  
Diphenhydramine citrate, 38 mg  
Pain Reliever (NSAID) /  
Nighttime Sleep-Aid

4 COATED  
CAPLETS\*  
Advil<sup>®</sup> PM

### Drug Facts (continued)

- 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 caplets at bedtime
- do not take more than 2 caplets in 24 hours

### Drug Facts (continued)

#### 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

calcium stearate, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C blue no. 2 aluminum lake, glyceryl behenate, hypromellose, lactose monohydrate, microcrystalline cellulose, pharmaceutical ink, polydextrose, polyethylene glycol, pregelatinized starch, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

#### Questions or comments?

Call weekdays 9 AM to 5 PM EST at 1-800-88-ADVIL

4 COATED  
CAPLETS\*  
Advil<sup>®</sup> PM

Ibuprofen, 200 mg /  
Diphenhydramine citrate, 38 mg  
Pain Reliever (NSAID) /  
Nighttime Sleep-Aid

### Drug Facts (continued)

- 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

### Drug Facts (continued)

- 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

Do Not Use if pouch is broken or torn.

For most recent product information, visit [www.Advil.com](http://www.Advil.com)



Pfizer, Madison, NJ 07940 USA  
© 2012 Pfizer Inc. U.S. Patent Pending

Repackaged and distributed with permission of Pfizer Consumer Healthcare by:  
Lil' Drug Store Products, Inc., 1201 Continental Place NE, Cedar Rapids, IA 52402  
1-877-507-6516 (M-F 8AM-4:30PM CST) [www.lildrugstore.com](http://www.lildrugstore.com) 97332C-US-07-10-3

EXP  
LOT





## ADVIL PM

ibuprofen and diphenhydramine citrate tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66715-9733
<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 citrate</b> (UNII: 4OD433S209) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine citrate	38 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>calcium stearate</b> (UNII: 776XM7047L)	
<b>carnauba wax</b> (UNII: R12CBM0EIZ)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>croscarmellose sodium</b> (UNII: M28OL1HH48)	
<b>FD&amp;C blue no. 2</b> (UNII: L06K8R7DQK)	
<b>aluminum oxide</b> (UNII: LM26O6933)	
<b>glyceryl dibehenate</b> (UNII: R8WTH25YS2)	
<b>hypromellose, unspecified</b> (UNII: 3NXW29V3WO)	
<b>lactose monohydrate</b> (UNII: EWQ57Q8I5X)	
<b>microcrystalline cellulose</b> (UNII: OP1R32D61U)	
<b>polydextrose</b> (UNII: VH2XOU12IE)	
<b>polyethylene glycol, unspecified</b> (UNII: 3WJQ0SDW1A)	
<b>sodium lauryl sulfate</b> (UNII: 368GB5141J)	
<b>stearic acid</b> (UNII: 4ELV7Z65AP)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL (Capsule-Shaped, Smooth in texture w/ polish surface)	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	Advil;PM
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:66715-9733-2	2 in 1 CARTON	05/11/20 10	11/25/20 18
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:66715-9733-8	5 in 1 CARTON	05/11/20 10	11/25/20 18
2		2 in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021394	05/11/20 10	11/25/20 18

**Labeler** - Lil' Drug Store Products, Inc. (093103646)

## Establishment

Name	Address	ID/FEI	Business Operations
CCB Packaging Inc.		362374464	REPACK(66715-9733) , RELABEL(66715-9733)

## Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Consumer Healthcare		828831730	LABEL(66715-9733)

Revised: 11/2017

Lil' Drug Store Products, Inc.