ADVIL PM- ibuprofen and diphenhydramine citrate tablet, coated ADVIL PM, TRAVEL BASIX- ibuprofen and diphenhydramine citrate tablet, coated

ADVIL PM, CVP HEALTH- ibuprofen and diphenhydramine citrate tablet, coated

Lil' Drug Store Products, Inc.

Advil $^{\otimes}$ PM Lil' Drug Store $^{\otimes}$, TRAVEL BASIX, CVP $_{\otimes}$ HEALTH

Drug Facts

Nighttime sleep-aid
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

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.

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

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Lil' Drug Store Products, Inc., 1201 Continental Place NE, Cedar Rapids, IA 52402

Advil PM, 6ct, Lil Drug Store ® - PDP/Package

Advil[®] PM

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

[caplet image]

6

Coated Caplets*

*Capsule-Shaped Tablets

[Lil' Drug Store ® logo]



Advil PM, 4ct TRAVEL BASIX - PDP/Package Advil PM

Ibuprofen, 200 mg/

Diphenhydramine Citrate, 38 mg

Pain Reliever (NSAID)/

Nighttime Sleep-Aid

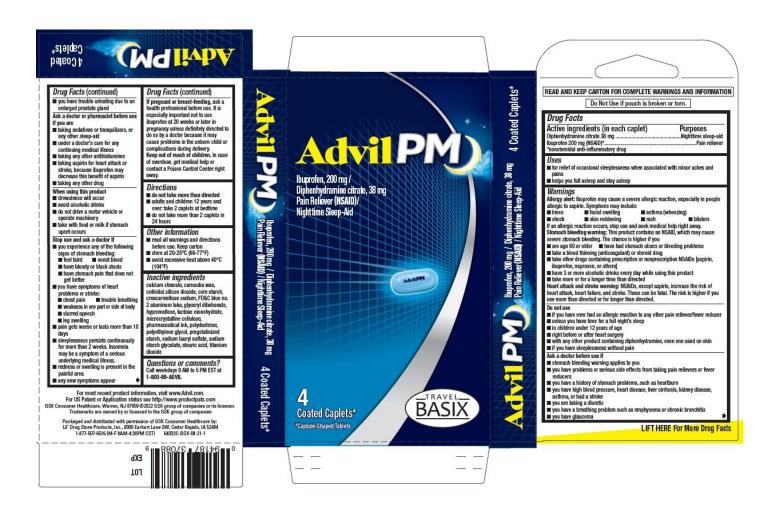
[caplet image]

4

Coated Caplets*

*Capsule-Shaped Tablets

[TRAVEL BASIX logo]



Advil PM 4ct, CVP ® HEALTH - PDP/Package



Advil PM

Ibuprofen, 200 mg/
Diphenhydramine Citrate, 38 mg
Pain Reliever (NSAID)/
Nighttime Sleep-Aid
[caplet image]

Coated Caplets*

*Capsule-Shaped Tablets

[CVP® HEALTH logo]

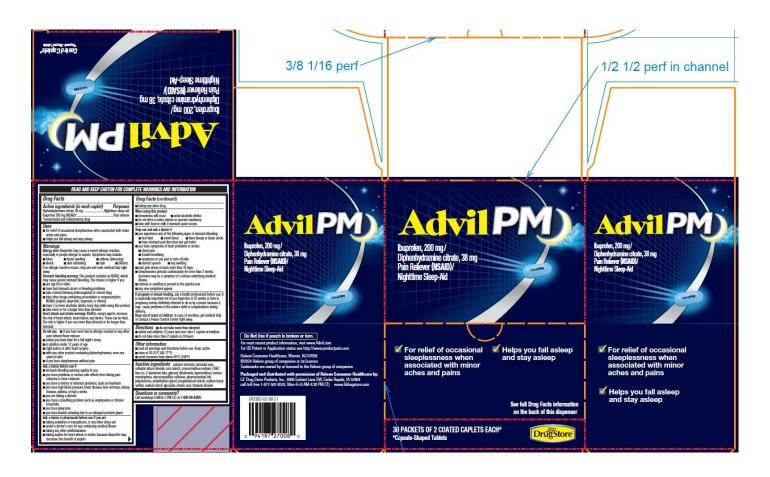
AdvilPM 30pc Dispens-It Box, Lil' Drug Store ® AdvilPM

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

[caplet image]

For relief of occasional
sleeplessness when
associated with minor aches and pains
Helps you fall asleep
and stay asleep
See full Drug Facts information
on the back of this dispenser
30 PACKETS OF 2 COATED CAPLETS EACH*
*Capsule-Shaped Tablets

[Lil' Drug Store® logo]



ADVIL PM

ibuprofen and diphenhydramine citrate tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-9633	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg		
DIPHENHYDRAMINE CITRATE (UNII: 40D433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg		

Inactive Ingredients		
Ingredient Name	Strength	
CALCIUM STEARATE (UNII: 776XM7047L)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)		
STARCH, CORN (UNII: O8232NY3SJ)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
ALUMINUM OXIDE (UNII: LMI26O6933)		
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)		

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

P	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:66715- 9633-3	30 in 1 BOX, UNIT-DOSE	04/19/2022		
1		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	04/19/2022	

ADVIL PM

ibuprofen and diphenhydramine citrate tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-9733	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg	
DIPHENHYDRAMINE CITRATE (UNII: 40D433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg	

Inactive Ingredients

Ingredient Name	Strength
CALCIUM STEARATE (UNII: 776XM7047L)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:66715- 9733-2	2 in 1 CARTON	05/11/2010		
1		2 in 1 POUCH; Type 0: Not a Combination Product			
2	NDC:66715- 9733-8	5 in 1 CARTON	05/11/2010	11/25/2018	
2		2 in 1 POUCH; Type 0: Not a Combination Product			
3	NDC:66715- 9733-3	3 in 1 CARTON	02/14/2018		
3		2 in 1 POUCH; Type 0: Not a Combination Product			

Marketing Information			
Marketing Application Number or Monograph Marketing Start Marketing En Category Citation Date Date			
NDA	NDA021394	05/11/2010	

ibuprofen and diphenhydramine citrate tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6433
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg		
DIPHENHYDRAMINE CITRATE (UNII: 40D433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE CITRATE	38 mg		

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
STARCH, CORN (UNII: O8232NY3SJ)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
ALUMINUM OXIDE (UNII: LMI26O6933)		
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
CALCIUM STEARATE (UNII: 776XM7047L)		
POLYDEXTROSE (UNII: VH2XOU12IE)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

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

# Item Code Package Description Marketing Start Date 1 NDC:66715-6433-2 2 in 1 CARTON 11/15/2022	Packaging					
	Item Code	de Package Description	_	Marketing End Date		
		2 in 1 CARTON	11/15/2022			
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 11/15/2022

ADVIL PM, CVP HEALTH

ibuprofen and diphenhydramine citrate tablet, coated

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-6533		
Route of Administration	ORAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg		
	DIPHENHYDRAMINE CITRATE	38 mg		

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CALCIUM STEARATE (UNII: 776XM7047L)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:66715- 6533-2	2 in 1 CARTON	05/06/2022			
1		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	05/06/2022	

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

Revised: 11/2024 Lil' Drug Store Products, Inc.