ADVIL PM- diphenhydramine citrate and ibuprofen tablet, coated
Haleon US Holdings LLC

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 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 ingredients

- 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 dibehenate, 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**

Additional Information

Do Not Use if seal under bottle cap imprinted with “SEALED for YOUR PROTECTION” is broken or missing.

For most recent product information, visit www.Advil.com.

Distributed by: GSK Consumer Healthcare, Warren, NJ 07059

Principal Display Panel

NDC 0573-0164-20

Advil *PM*

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

20
Coated Caplets*
**Capsule-Shaped Tablets*

ADVIL PM

diphenhydramine citrate and ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0573-0164
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
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)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (blue)	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	Advil;PM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0164-33	1 in 1 CARTON	12/21/2005	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0573-0164-04	4 in 1 POUCH; Type 0: Not a Combination Product	12/21/2005	
3	NDC:0573-0164-20	1 in 1 CARTON	12/21/2005	
3		20 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0573-0164-30	1 in 1 CARTON	12/21/2005	

4		40 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0573-0164-40	1 in 1 CARTON	12/21/2005	
5		80 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0573-0164-43	1 in 1 CARTON	12/21/2005	
6		120 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0573-0164-45	1 in 1 CARTON	12/21/2005	
7		180 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:0573-0164-32	1 in 1 CARTON	12/21/2005	
8		50 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:0573-0164-41	1 in 1 CARTON	12/21/2005	
9		100 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:0573-0164-91	3000 in 1 BOX	12/21/2005	
10		2 in 1 POUCH; Type 0: Not a Combination Product		
11	NDC:0573-0164-05	2 in 1 CARTON	12/21/2005	
11		2 in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:0573-0164-55	50 in 1 TRAY	12/21/2005	
12		2 in 1 POUCH; Type 0: Not a Combination Product		
13	NDC:0573-0164-21	1 in 1 CARTON	12/21/2005	
13		30 in 1 BOTTLE; Type 0: Not a Combination Product		
14	NDC:0573-0164-44	1 in 1 CARTON	12/21/2005	
14		140 in 1 BOTTLE; Type 0: Not a Combination Product		
15	NDC:0573-0164-14	2 in 1 CARTON	12/21/2005	
15		2 in 1 POUCH; Type 0: Not a Combination Product		
16	NDC:0573-0164-12	6 in 1 CARTON	12/21/2005	
16		2 in 1 POUCH; Type 0: Not a Combination Product		
17	NDC:0573-0164-49	1 in 1 CARTON	12/21/2005	
17		200 in 1 BOTTLE; Type 0: Not a Combination Product		
18	NDC:0573-0164-46	1 in 1 CARTON	12/21/2005	
18		180 in 1 BOTTLE; Type 0: Not a Combination Product		
19	NDC:0573-0164-65	120 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2016	

20	NDC:0573-0164-08	1 in 1 PACKAGE	03/17/2017	
20		8 in 1 VIAL; Type 0: Not a Combination Product		
21	NDC:0573-0164-09	8 in 1 VIAL; Type 0: Not a Combination Product	03/17/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021394	12/21/2005	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 4/2024 Haleon US Holdings LLC