

**ADVIL ALLERGY SINUS- chlorpheniramine maleate, ibuprofen,
pseudoephedrine hcl tablet, coated**
Haleon US Holdings LLC

Drug Facts

Active ingredients (in each caplet)

Chlorpheniramine maleate 2 mg

Ibuprofen 200 mg (NSAID)*

Pseudoephedrine HCl 30 mg

*nonsteroidal anti-inflammatory drug

Purposes

Antihistamine

Pain reliever/fever reducer

Nasal decongestant

Uses

temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:

- runny nose
- itchy, watery eyes
- itching of the nose or throat
- sneezing
- nasal congestion
- sinus pressure
- headache
- minor aches and pains
- fever

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

- in children under 12 years of age
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if

- you have a breathing problem such as emphysema or chronic bronchitis
- 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, thyroid disease, diabetes, glaucoma, trouble urinating due to an enlarged prostate gland, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking sedatives or tranquilizers
- taking any other product that contains pseudoephedrine, chlorpheniramine or any other nasal decongestant or antihistamine
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness

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
- fever gets worse or lasts more than 3 days
- nasal congestion lasts for more than 7 days
- redness or swelling is present in the painful area
- you get nervous, dizzy, or sleepless
- symptoms continue or get worse
- 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**
- **the smallest effective dose should be used**
- adults: take 1 caplet every 4-6 hours while symptoms persist.
- do not take more than 6 caplets in any 24-hour period, unless directed by a doctor
- children under 12 years of age: do not use

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

carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, glyceryl behenate, hypromellose, microcrystalline cellulose, pharmaceutical ink, polydextrose, polyethylene glycol, pregelatinized starch, silicon dioxide, titanium dioxide

Questions or comments?

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

Additional Information

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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

Product inside sealed in plastic blister with foil backing.

Do Not Use if plastic blister or foil barrier is broken.

Dist. By: GSK Consumer Healthcare, Warren, NJ 07059

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PRINCIPAL DISPLAY PANEL

Advil

ALLERGY SINUS

Ibuprofen 200 mg ➤ Pain Reliever/Fever Reducer (NSAID)

Pseudoephedrine HCl 30 mg ➤ Nasal Decongestant

Chlorpheniramine Maleate 2 mg ➤ Antihistamine

Relieves Runny Nose, Nasal Congestion, Sneezing,
Itchy, Watery Eyes, Headache and Sinus Pressure

ONLY

1

PILL

EVERY

4-6

HOURS

Advil

A/S

20 COATED CAPLETS*

*Capsule-Shaped Tablets

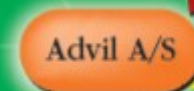
PAA148681 Carton

Advil

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ADVIL ALLERGY SINUS

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-0188
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients				
Ingredient Name			Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)				
STARCH, CORN (UNII: O8232NY3SJ)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
Product Characteristics				
Color	orange (bright orange)	Score	no score	
Shape	OVAL (oval shaped tablet)	Size	15mm	
Flavor		Imprint Code	Advil;A;S	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0188-10	20 in 1 CARTON	12/20/2002	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA021441	12/20/2002	

Labeler - Haleon US Holdings LLC (079944263)