

**ADVIL ALLERGY SINUS- chlorpheniramine maleate, ibuprofen, pseudoephedrine hcl tablet, coated**

**GlaxoSmithKline Consumer Healthcare Holdings (US) LLC**

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***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 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**
- **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**

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

## **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**

**20**

**COATED**

**CAPLETS\***

\*Capsule-Shaped Tablets

Product inside sealed in plastic blister with foil backing.  
Do Not Use if plastic blister or foil backing is broken.

DRUG FACTS  
LABELING AREA

From Medeva, Inc. (USA) © 2016 Medeva, Inc.  
For most recent product information, call 1-800-AD-5050  
U.S. Patent number 7,963,287

**Advil** ALLERGY SINUS

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**Advil** ALLERGY SINUS

**Advil**<sup>®</sup>

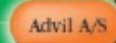
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**ONLY 1 PILL EVERY 4-6 HOURS**

**20 COATED CAPLETS\***

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



\*Capsule-Shaped Tablets

FPO 128 Code  
080245

FPO 128 Code  
080245

**Advil** ALLERGY SINUS

→ **READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION**

**Drug Facts** | **Drug Facts (continued)**

**LIFT HERE**  
For More Drug Facts



**Active Ingredients  
(in each caplet)**

Chlorpheniramine maleate 2 mg .....Antihistamine  
 Ibuprofen 200 mg (NSAID)\* ... Pain reliever/fever reducer  
 Pseudoephedrine HCl 30 mg ..... Nasal decongestant  
 \*nonsteroidal anti-inflammatory drug

**Purposes****Uses**

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

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**Drug Facts (continued)****Do not use**

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**Drug Facts (continued)**

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**Drug Facts (continued)****Other information**

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**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?**

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chlorpheniramine maleate, ibuprofen, pseudoephedrine hcl tablet, coated

**Product Information**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GLYCERYL DIBEHENATE</b> (UNII: R8WTH25YS2)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

**Product Characteristics**

<b>Color</b>	ORANGE (bright orange)	<b>Score</b>	no score
<b>Shape</b>	OVAL (oval shaped tablet)	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	Advil;A;S
<b>Contains</b>			

**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**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA021441	12/20/2002	

**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

**Registrant** - Pfizer Inc (113480771)

**Establishment**

Name	Address	ID/FEI	Business Operations
Wyeth Pharmaceuticals Company		829390975	ANALYSIS(0573-0188) , LABEL(0573-0188) , MANUFACTURE(0573-0188) , PACK(0573-0188)

Revised: 11/2020

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC