

**ADVIL COLD AND SINUS- ibuprofen, pseudoephedrine hydrochloride capsule, liquid filled**  
**Wyeth Consumer Healthcare LLC**

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**ADVIL COLD & SINUS**  
**(ibuprofen and pseudoephedrine HCl)**

**DRUG FACTS**

**ACTIVE INGREDIENTS (IN EACH LIQUID-FILLED CAPSULE)**

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)\*

(present as the free acid and potassium salt)

Pseudoephedrine HCl 30 mg

\*nonsteroidal anti-inflammatory drug

**PURPOSES**

Pain reliever/fever reducer

Nasal decongestant

**USES**

temporarily relieves these symptoms associated with the common cold or flu:

- headache
- fever
- sinus pressure
- nasal congestion
- minor body aches and pains

**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**

- 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, have 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 any other product that contains pseudoephedrine or any other nasal decongestant
- 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

### **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
- symptoms continue or get worse
- redness or swelling is present in the painful area
- you get nervous, dizzy, or sleepless
- 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 and children 12 years of age and over:
  - take 1 capsule every 4 to 6 hours while symptoms persist. If symptoms do not respond to 1 capsule, 2 capsules may be used.
  - do not use more than 6 capsules in any 24-hour period unless directed by a doctor
- children under 12 years of age: do not use

### **OTHER INFORMATION**

- each capsule contains: **potassium 20 mg**
- store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).
- read all warnings and directions before use. Keep carton.

### **INACTIVE INGREDIENTS**

D&C yellow no. 10, FD&C red no. 40, gelatin, medium-chain triglycerides, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution

### **QUESTIONS OR COMMENTS?**

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

### **PRINCIPAL DISPLAY PANEL - 200 mg/30 mg Capsule Blister Pack Carton**

**Advil®**

### **COLD & SINUS Non-Drowsy**

Ibuprofen 200 mg □ Pain Reliever/Fever Reducer (**NSAID**)

Pseudoephedrine HCl 30 mg □ Nasal Decongestant

**Relieves Sinus Pressure,  
Nasal Congestion and Fever**

**LIQUI-GELS®**

**32 LIQUID-FILLED CAPSULES**



**ADVIL<sup>®</sup> LIQUID-GELS<sup>®</sup>**  
**COLD & SINUS**

**Advil**

**Drug Facts (continued)**

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  - slurred speech
  - leg swelling
- fever gets worse or lasts more than 3 days
- nasal congestion lasts for more than 7 days
- symptoms continue or get worse
- redness or swelling is present in the painful area
- you get nervous, dizzy, or sleepless
- 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.

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**Drug Facts (continued)**

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- right before or after heart surgery
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- taking any other product that contains pseudoephedrine or any other nasal decongestant
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit or aspirin
- taking any other drug

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Drug Facts

Active ingredients

Purposes

Warnings

Drug Facts (continued)

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

# Advil<sup>®</sup>

## COLD & SINUS Non-Drowsy

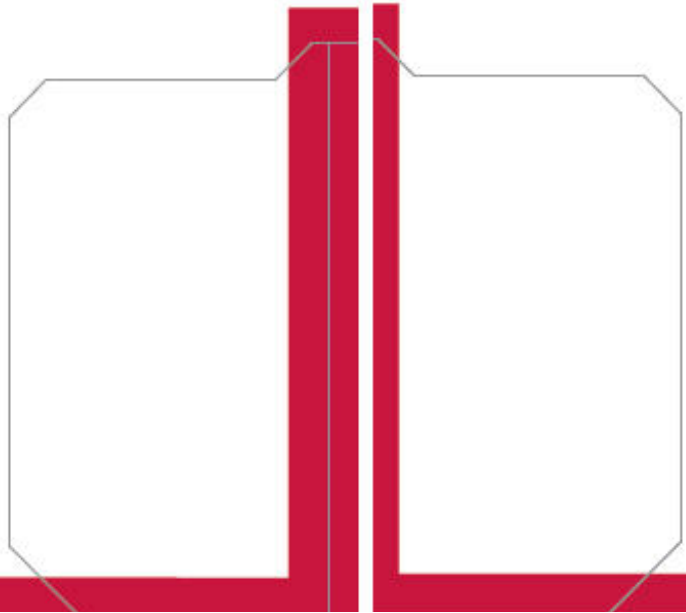
Ibuprofen 200 mg > Pain Reliever/Fever Reducer (NSAID)  
Pseudoephedrine HCl 30 mg > Nasal Decongestant

Relieves Sinus Pressure,  
Nasal Congestion and Fever

**LIQUI-GELS<sup>®</sup>**



32 LIQUID-FILLED CAPSULES





Relieves Sinus Pressure, Nasal Congestion and Fever

**Advil**<sup>®</sup> COLD & SINUS LIQUI-GELS<sup>®</sup>



**Advil**<sup>®</sup> COLD & SINUS LIQUI-GELS<sup>®</sup>

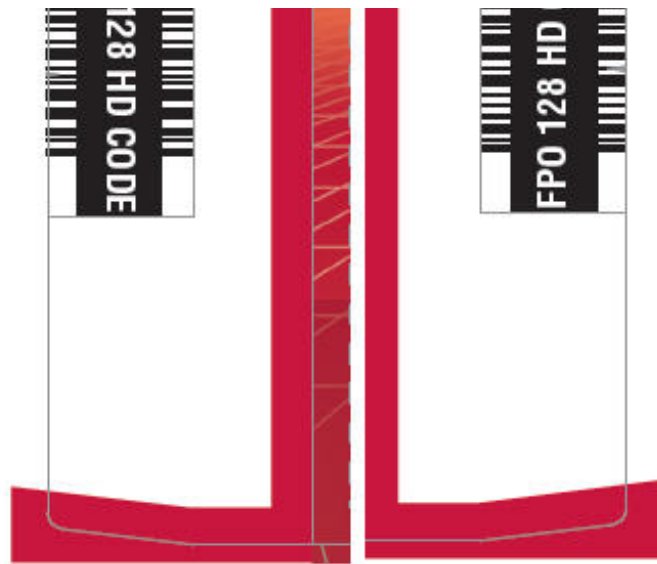
PAA081954



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

For most recent product information, visit [www.advil.com](http://www.advil.com)  
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## ADVIL COLD AND SINUS

ibuprofen, pseudoephedrine hydrochloride capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0573-0184
<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>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

### Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	Advil;C;S



**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-0184-32	32 in 1 CARTON	05/30/2002	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0573-0184-16	16 in 1 CARTON	05/30/2002	
2		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	NDA021374	05/30/2002	

**Labeler** - Wyeth Consumer Healthcare LLC (828831730)**Registrant** - Pfizer Inc (113480771)

Revised: 4/2017

Wyeth Consumer Healthcare LLC