

**ADVIL COLD AND SINUS- ibuprofen and pseudoephedrine hydrochloride tablet, coated  
Haleon US Holdings LLC**

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**Drug Facts**

**Active ingredients (in each caplet)**

Ibuprofen 200 mg (NSAID)\*

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 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 us if**

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducer
- 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 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 and children 12 years of age and over:
  - take 1 caplet every 4 to 6 hours while symptoms persist. If symptoms do not respond to 1 caplet, 2 caplets may be used.
  - do not use 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**

- Store at room temperature not exceeding 30°C
- read all warnings and directions before use. Keep carton.

### **Inactive ingredients**

acetylated monoglycerides, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, methylparaben, microcrystalline cellulose, pharmaceutical glaze,

pharmaceutical ink, povidone, pregelatinized starch, propylparaben, sodium benzoate, sodium lauryl sulfate, stearic acid, sucrose, synthetic iron oxides, titanium dioxide

**Questions or comments?**

Contact us at [www.haleon.com](http://www.haleon.com) Adverse event reporting to  
[farmacovigilanciacar@haleon.com](mailto:farmacovigilanciacar@haleon.com) Complaints reporting to [pqc.caricam@gsk.com](mailto:pqc.caricam@gsk.com)

**Additional Information**

**Do Not Use if sealed pouch is broken or torn.**

**Package/Label Principal Display Panel**

**Advil®**

**Cold & Sinus**

IBUPROFEN 200mg ▶ ▶ Pain Reliever / Fever Reducer **(NSAID)**

PSEUDOEPHEDRINE HCl 30mg ▶ ▶ Nasal Decongestant

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

**50 Pouches of 2 Coated Caplets\***

**\*Oval-Shaped Tablets**

# Advil<sup>®</sup> Cold & Sinus

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## ADVIL COLD AND SINUS

ibuprofen and pseudoephedrine hydrochloride tablet, coated

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:0573-0180 |
| Route of Administration | 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>DIACETYLATED MONOGLYCERIDES</b> (UNII: 5Z17386USF) |          |
| <b>CARNAUBA WAX</b> (UNII: R12CBM0E1Z)                |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)             |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                |          |
| <b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)       |          |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)               |          |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)  |          |
| <b>HELLAC</b> (UNII: 46N107B71O)                      |          |
| <b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)       |          |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)               |          |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)             |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)       |          |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                |          |
| <b>SUCROSE</b> (UNII: C151H8M554)                     |          |
| <b>FERROUS OXIDE</b> (UNII: G7036X8B5H)               |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)            |          |

## Product Characteristics

|                 |                      |                     |                  |
|-----------------|----------------------|---------------------|------------------|
| <b>Color</b>    | BROWN (butterscotch) | <b>Score</b>        | no score         |
| <b>Shape</b>    | OVAL (oblong)        | <b>Size</b>         | 14mm             |
| <b>Flavor</b>   |                      | <b>Imprint Code</b> | Advil;Cold;Sinus |
| <b>Contains</b> |                      |                     |                  |

## Packaging

| # | Item Code        | Package Description                             | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0573-0180-39 | 50 in 1 CARTON                                  | 02/02/2026           |                    |
| 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 |
|--------------------|--|----------------------|--------------------|
| Export only        |  | 02/02/2026           |                    |

Revised: 2/2026

Haleon US Holdings LLC