

ADVIL SINUS CONGESTION AND PAIN- ibuprofen, phenylephrine hydrochloride tablet, coated
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Drug Facts

Active ingredients (in each tablet)

Ibuprofen 200 mg (NSAID)*

Phenylephrine HCl 10 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
- reduces swelling of the nasal passages
- temporarily restores freer breathing through the nose

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 because this product contains too much medication for children under this 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 phenylephrine 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
- pain gets worse or lasts more than 7 days
 - 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**
- adults and children 12 years of age and over:
 - take 1 tablet every 4 hours while symptoms persist.
 - do not use more than 6 tablets in any 24-hour period unless directed by a doctor
- children under 12 years of age: do not use because this product contains too much medication for children under this age

Other information

- 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

acesulfame potassium, artificial flavor, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, glycerin, hypromellose, lactic acid, lecithin, maltodextrin, medium-chain triglycerides, microcrystalline cellulose, pharmaceutical ink, polydextrose, polyvinyl alcohol, pregelatinized starch, propyl gallate, sodium lauryl sulfate, stearic acid, sucralose, synthetic iron oxide, talc, titanium dioxide, triacetin, xanthan gum

Questions or comments?

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

Additional Information

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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

Distributed by: GSK Consumer Healthcare, Warren, NJ 07059

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

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PRINCIPAL DISPLAY PANEL

Advil

NON-DROWSY

**SINUS
CONGESTION & PAIN**

Ibuprofen 200 mg Pain Reliever/Fever Reducer **(NSAID)**
Phenylephrine HCl 10 mg Nasal Decongestant

- Nasal Congestion
- Headache
- Sinus Pressure
- Fever
- Nasal Swelling
- Body Aches

**ONE
TABLET
DOSE!**

1200-P10

30 Coated Tablets

000065893

NON-DROWSY

Advil

**50% MORE
10 FREE
Tablets**

SINUS CONGESTION & PAIN

**Ibuprofen 200 mg Pain Reliever/Fever Reducer (NSAID)
Phenylephrine HCl 10 mg Nasal Decongestant**

- ✓ Nasal Congestion
- ✓ Sinus Pressure
- ✓ Nasal Swelling
- ✓ Headache
- ✓ Fever
- ✓ Body Aches

**ONE
TABLET
DOSE!**

30/20 Coated Tablets



ADVIL SINUS CONGESTION AND PAIN

ibuprofen, phenylephrine hydrochloride tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0573-0199 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-----------------------------|----------|
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 200 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |

| |
|--|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) |
| STARCH, CORN (UNII: O8232NY3SJ) |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) |
| LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT) |
| EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV) |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) |
| POLYDEXTROSE (UNII: VH2XOU12IE) |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) |
| PROPYL GALLATE (UNII: 8D4SNN7V92) |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) |
| STEARIC ACID (UNII: 4ELV7Z65AP) |
| SUCRALOSE (UNII: 96K6UQ3ZD4) |
| FERRIC OXIDE RED (UNII: 1K09F3G675) |
| TALC (UNII: 7SEV7J4R1U) |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) |
| TRIACETIN (UNII: XHX3C3X673) |
| XANTHAN GUM (UNII: TTV12P4NEE) |

Product Characteristics

| | | | |
|-----------------|-------------|---------------------|----------|
| Color | BROWN (tan) | Score | no score |
| Shape | OVAL | Size | 15mm |
| Flavor | | Imprint Code | 1200;P10 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0573-0199-11 | 10 in 1 CARTON | 07/01/2015 | |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0573-0199-21 | 20 in 1 CARTON | 07/01/2015 | |
| 2 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:0573-0199-01 | 50 in 1 TRAY | 07/01/2015 | |
| 3 | | 1 in 1 POUCH; Type 0: Not a Combination Product | | |
| 4 | NDC:0573-0199-22 | 30 in 1 CARTON | 11/02/2015 | |
| 4 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 5 | NDC:0573-0199-03 | 3000 in 1 CARTON | 07/01/2015 | |
| 5 | | 1 in 1 POUCH; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | NDA022565 | 07/01/2015 | |

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|---|
| Wyeth Pharmaceuticals Company | | 829390975 | ANALYSIS(0573-0199) , LABEL(0573-0199) , MANUFACTURE(0573-0199) , PACK(0573-0199) |

Revised: 12/2022

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC