IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE - ibuprofen and pseudoephedrine hydrochloride tablet, coated
Aurohealth LLC

Ibuprofen and Pseudoephedrine Hydrochloride Tablets USP 200 mg/30 mg

Drug Facts

Active ingredients (in each caplet)

Ibuprofen USP 200 mg (NSAID)*

Pseudoephedrine hydrochloride USP 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 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 (1-800-222-1222) 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 20° to 25°C (68° to 77°F). Avoid excessive heat above 40ºC (104ºF).
- read all warnings and directions before use. Keep carton.

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, glyceryl monocaprylocaprate type 1, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyvinyl alcohol-part. hydrolyzed, pregelatinized starch (maize), sodium lauryl sulfate, stearic acid, talc and titanium dioxide.

Questions or comments? call **1-855-274-4122**
(Monday - Friday 8:30 AM to 5:00 PM EST)

Distributed by:
AUROHEALTH LLC
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg/30 mg (32 Tablets)

AUROHEALTH
NDC 58602-839-13
#Compare to the active
ingredients of Advil® Cold &Sinus

Non-Drowsy
COLD & SINUS RELIEF
Ibuprofen and Pseudoephedrine
Hydrochloride Tablets USP 200 mg/30 mg
Ibuprofen USP 200 mg - Pain Reliever/Fever Reducer (NSAID)
Pseudoephedrine Hydrochloride USP 30 mg - Nasal Decongestant

- Relieves Sinus Pressure
- Nasal Congestion and Fever

32 Coated Caplets†
†Oval-Shaped tablets

IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE

ibuprofen and pseudoephedrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-839
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLYCERYL MONO- AND DICAPRYLOCAPRATE (UNII: U72Q2I8C85)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN (Light brown to brown)	**Score**	no score
Shape	OVAL (Biconvex)	**Size**	14mm
Flavor		**Imprint Code**	70;L
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-839-13	4 in 1 CARTON	03/10/2023	
1		8 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
ANDA	ANDA213565	03/10/2023	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations

Aurobindo Pharma Limited		650381903	ANALYSIS(58602-839) , MANUFACTURE(58602-839)