

IBUPROFEN COLD AND SINUS A P J- ibuprofen, pseudoephedrine hydrochloride tablet, coated

A P J Laboratories Limited

IBUPROFEN

PSEUDOEPHEDRINE HYDROCHLORIDE

Pain reliever/Fever reducer

Nasal decongestant

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222).

uses

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

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

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

- 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.

if you have ever had an allergic reaction to any other pain reliever/fever reducer

•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.

- in children under 12 years of age
- right before or after heart surgery
- CALCIUM CARBONATE
- STARCH, CORN
- METHYLPARABEN
- PROPYLPARABEN
- SODIUM STARCH GLYCOLATE TYPE A POTATO
- TALC
- MAGNESIUM STEARATE
- SILICON DIOXIDE
- CROSCARMELLOSE SODIUM
- SODIUM LAURYL SULFATE
- ISOPROPYL ALCOHOL
- METHYLENE CHLORIDE
- TITANIUM DIOXIDE



IBUPROFEN COLD AND SINUS A P J

ibuprofen, pseudoephedrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46084-091
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	20 mg
STARCH, CORN (UNII: O8232NY3SJ)	8 mg
METHYL PARABEN (UNII: A2I8C7HI9T)	.5 mg
PROPYL PARABEN (UNII: Z8IX2SC1OH)	.2 mg
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	6 mg
TALC (UNII: 7SEV7J4R1U)	4 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	3 mg
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	1 mg
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	1.5 mg
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	1 mg

ISOPROPYL ALCOHOL (UNII: ND2M416302)	60 mg
METHYLENE CHLORIDE (UNII: 588X2YUY0A)	150 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	1.5 mg

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	15mm
Flavor		Imprint Code	091
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46084-091-60	20 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074567	06/01/2013	

Labeler - A P J Laboratories Limited (677378339)

Registrant - A P J Laboratories Limited (677378339)

Establishment

Name	Address	ID/FEI	Business Operations
A P J Laboratories Limited		677378339	manufacture(46084-091)

Revised: 4/2013

A P J Laboratories Limited