

IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE- ibuprofen and pseudoephedrine hydrochloride tablet, sugar coated
Topco Associates LLC

Drug Facts

ACTIVE INGREDIENTS (IN EACH CAPLET)

Ibuprofen, USP 200 mg (NSAID)*

Pseudoephedrine HCl, 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:

- fever
- sinus pressure
- nasal congestion
- headache
- 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

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

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 or have trouble urinating due to an enlarged prostate gland
- 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 drug
- 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

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- symptoms continue or get worse
- any new symptoms appear
- you get nervous, dizzy, or sleepless
- fever gets worse or lasts more than 3 days
- nasal congestion lasts for more than 7 days
- redness or swelling is present in the painful area

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 (1-800-222-1222).

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 - 25° C (68 - 77° F). Avoid excessive heat above 40° C (104° F).
- read all warnings and directions before use. Keep carton.
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**

INACTIVE INGREDIENTS

Acacia, calcium carbonate, carnauba wax, confectioner's sugar, corn starch, croscarmellose sodium, crospovidone, FD&C Blue no. 2 Aluminum Lake, FD&C Red no. 40 Aluminum Lake, FD&C Yellow no. 6 Aluminum Lake, gelatin, guar gum, hydrogenated vegetable oil, hydroxypropyl cellulose, iron oxide black, kaolin, polyethylene glycol, powdered cellulose, povidone, pregelatinized starch, propylene glycol, shellac, silicon dioxide, sodium benzoate, sucrose, talc, titanium dioxide, white wax

QUESTIONS?

call 1-888-423-0139

PRINCIPAL DISPLAY PANEL

TopCare®

NDC 36800-423-21

NON-DROWSY

Ibuprofen

Cold & Sinus

IBUPROFEN AND PSEUDOEPHEDRINE HCl TABLETS, USP

Ibuprofen, USP 200 mg · Pain Reliever/Fever Reducer (NSAID)*

Pseudoephedrine HCl, USP 30 mg · Nasal Decongestant

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

20 COATED CAPLETS[†]

[†]OVAL-SHAPED TABLETS

COMPARE TO ADVIL® COLD & SINUS active ingredients^{††}

***NONSTEROIDAL ANTI-INFLAMMATORY DRUG**

DISTRIBUTED BY TOPCO ASSOCIATES LLC

5095196/R0412



Expiration Date: _____
Batch No. _____

Non Varnish Area

Drug Facts (continued)

Uses temporarily relieves these symptoms associated with the common cold or flu: ■ fever ■ sinus pressure ■ nasal congestion

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ skin redness ■ rash ■ facial swelling ■ asthma (wheezing) ■ shock ■ hives ■ nasal congestion ■ sinus pressure ■ nasal congestion ■ headache ■ minor body aches and pains

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 thinner (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ take 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed

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

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 or have trouble urinating due to an enlarged prostate gland ■ 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 drug

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.

Drug Facts (continued)

■ 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

When using this product

■ take with food or milk if stomach upset occurs ■ the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ have bloody or black stools ■ vomit blood ■ have stomach pain that does not get better ■ symptoms continue or get worse ■ any new symptoms appear ■ you get nervous, dizzy, or sleepless ■ fever gets worse or lasts more than 3 days ■ nasal congestion lasts for more than 7 days ■ redness or swelling is present in the painful area

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 (1-800-222-1222).

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

Drug Facts

Active ingredients (in each caplet)

Ibuprofen, USP 200 mg (NSAID)*
Pseudoephedrine HCl, USP 30 mg
*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer
Nasal decongestant



NDC 36800-423-21

NON-DROWSY

Ibuprofen Cold & Sinus

IBUPROFEN AND PSEUDOEPHEDRINE HCl TABLETS, USP

**Ibuprofen, USP 200 mg • Pain Reliever/Fever Reducer (NSAID)*
Pseudoephedrine HCl, USP 30 mg • Nasal Decongestant**

• Relieves Sinus Pressure, Nasal Congestion and Fever



actual size

20 COATED CAPLETS†
†OVAL-SHAPED TABLETS



COMPARE TO ADVIL® COLD & SINUS active ingredients††

*NONSTEROIDAL ANTI-INFLAMMATORY DRUG

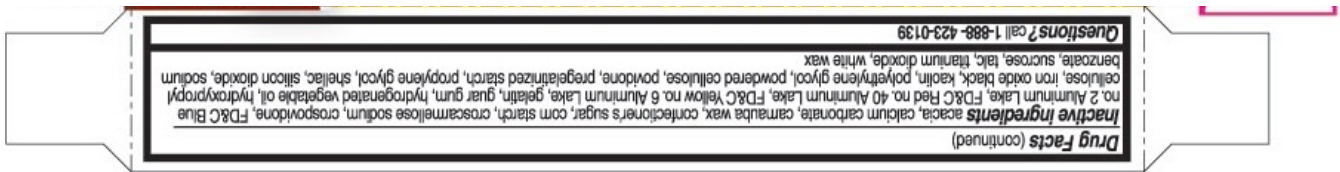
TopCare®

††This product is not manufactured or distributed by Wyeth Consumer Healthcare. R04112

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This TOP CARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

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IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE

ibuprofen and pseudoephedrine hydrochloride tablet, sugar coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-423
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
ACACIA (UNII: 5C5403N26O)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 68401960MK)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GUAR GUM (UNII: E89I1637KE)	
TRISTEARIN (UNII: P6OCJ2551R)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	

Product Characteristics			
Color	brown	Score	no score
Shape	OVAL (Caplets)	Size	14mm
Flavor		Imprint Code	423
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-423-21	20 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074567	10/08/2001	

Labeler - Topco Associates LLC (006935977)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment			
Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(36800-423)