IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE- ibuprofen and pseudoephedrine hydrochloride tablet, sugar coated
Ohm Laboratories Inc.

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
  - vomit blood
  - have bloody or black stools
  - 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 - 25º C (68 - 77º F). Avoid excessive heat above 40º C (104º 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 **1-800-406-7984**

PRINCIPAL DISPLAY PANEL

†Compare to the active ingredients of Advil® Cold & Sinus

NDC 51660-423-21

ohm®

Non-Drowsy

Cold & Sinus Relief

Ibuprofen and Pseudoephedrine HCl Tablets, USP

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

Pseudoephedrine HCl, USP 30 mg – Nasal Decongestant

Relieves Sinus Pain, Nasal Congestion and Fever

20 Coated Caplets**

(oval-shaped tablets)**

Distributed by: Ohm Laboratories Inc.

5089045/R0811

NDC 51660-423-21

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Non-Drowsy

Cold & Sinus Relief

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IBUPROFEN, USP 200 mg • PAIN RELIEVER/FEVER REDUCER (NSAID)*

PSEUDOEPHEDRINE HCl, USP 30 mg • NASAL DECONGESTANT

*nonsteroidal anti-inflammatory drug

20 Coated Caplets** (**oval-shaped tablets)

✔ Relieves Sinus Pressure, Nasal Congestion and Fever

Expiration Date:

Batch No.

Non Varnish Area

5089045

Drug Facts

Active Ingredients (in each caplet) — **Purposes**

Ibuprofen, USP 200 mg (NSAID)* ..... Pain reliever/Fever reducer

Pseudoephedrine HCl, USP 30 mg ..... Nasal decongestant

*nonsteroidal anti-inflammatory drug

Drug Facts (continued)

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 celecoxib] ■ have 3 or more alcoholic drinks every day while using this product.

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

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

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.

5089045

R0811

TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.

"This product is not manufactured or distributed by Wyeth Consumer Healthcare. Advil® is a registered trademark of Wyeth LLC.

Distributed by: Ohm Laboratories Inc.
1365 Livingston Avenue, North Brunswick, NJ 08902

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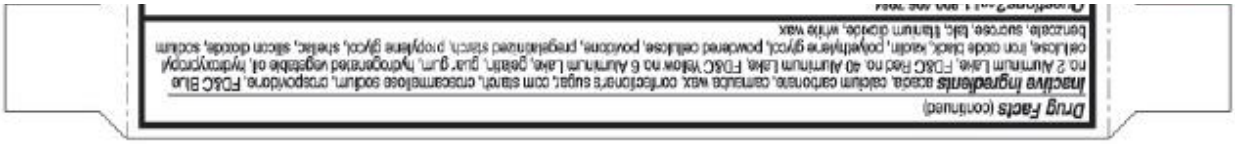

Drug Facts (continued)

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

IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE

ibuprofen and pseudoephedrine hydrochloride tablet, sugar coated

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:51660-423
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (IBUPROFEN)	IBUPROFEN	200 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (PSEUDOEPHEDRINE)	PSEUDOEPHEDRINE	30 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA	
CALCIUM CARBONATE	
CARNAUBA WAX	
STARCH, CORN	
CROSCARMELLOSE SODIUM	
CROSPOVIDONE	
FD&C BLUE NO. 2	
FD&C RED NO. 40	
FD&C YELLOW NO. 6	
GELATIN	
HYDROXYPROPYL CELLULOSE	
KAOLIN	
POVIDONE	
POWDERED CELLULOSE	
STARCH, PREGELATINIZED CORN	
PROPYLENE GLYCOL	
SHELLAC	
SILICON DIOXIDE	
SODIUM BENZOATE	
SUCROSE	
TALC	
TITANIUM DIOXIDE	
WHITE WAX	
GUAR GUM	
FERROSOFERRIC OXIDE	

POLYETHYLENE GLYCOLS	

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:51660-423-21	20 in 1 BLISTER PACK		
2	NDC:51660-423-41	40 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074567	10/13/2001	

Labeler - Ohm Laboratories Inc. (184769029)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(51660-423)

Revised: 1/2012 Ohm Laboratories Inc.