

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

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**Ibuprofen and Pseudoephedrine hydrochloride**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purposes</i></b>
Ibuprofen, USP 200 mg (NSAID)*	Pain reliever/fever reducer
Pseudoephedrine HCl, USP 30 mg	Nasal decongestant

\* nonsteroidal anti-inflammatory drug

**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 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.

### **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**

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

### **PRINCIPAL DISPLAY PANEL - 200 mg/30 mg Tablet Blister Pack Carton**

† **Compare To**  
**the active ingredients of**  
**Advil® Cold & Sinus**

**NDC 51660-493-41**

**See New Warnings Information**

**ohm®**

***Non-Drowsy***

**Cold & Sinus**

**Ibuprofen and Pseudoephedrine**  
**HCl Tablets, USP**

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

**\*nonsteroidal anti-inflammatory drug**

**• *Relieves Sinus Pressure,***

*Nasal Congestion and Fever*

**40 Coated Caplets\*\***

**(\*\*oval-shaped tablets)**

**Directions**

- do not take more than directed
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  - you get nervous, dizzy, or sleepless
  - any new symptoms appear

**Drug Facts (continued)**

**When using this product**

- take with food or milk if stomach upset occurs
- taking any other drug
- decrease this benefit of aspirin
- taking aspirin for heart attack or stroke, because ibuprofen may
- other nasal decongestant
- taking any other product that contains pseudoephedrine or any
- under a doctor's care for any serious condition

**Ask a doctor or pharmacist before use if you are**

- you are taking a diuretic
- urinating due to an enlarged prostate gland, or had a stroke
- kidney disease, asthma, thyroid disease, diabetes, have trouble
- you have high blood pressure, heart disease, liver cirrhosis,
- you have a history of stomach problems, such as heartburn
- relievers or fever reducers
- you have problems or serious side effects from taking pain
- stomach bleeding warning applies to you

**Ask a doctor before use if**

- an MAOI, ask a doctor or pharmacist before taking this product.
- the MAOI drug. If you do not know if your prescription drug contains conditions, or Parkinson's disease), or for 2 weeks after stopping (MAOI) (certain drugs for depression, psychiatric, or emotional
- if you are now taking a prescription monoamine oxidase inhibitor
- right before or after heart surgery
- reliever/fever reducer
- if you have ever had an allergic reaction to any other pain
- in children under 12 years of age

**Do not use**

- longer than directed.
- can be fatal. The risk is higher if you use more than directed or for
- increase the risk of heart attack, heart failure, and stroke. These
- Heart attack and stroke warning: NSAIDs, except aspirin,

**Drug Facts (continued)**

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especially in people allergic to aspirin. Symptoms may include:

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**Drug Facts (continued)**

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\*nonsteroidal anti-inflammatory drug

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NDC 51660-493-41

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**Non-Drowsy**

**ohm®**

**Cold & Sinus**

# Ibuprofen and Pseudoephedrine HCl Tablets, USP

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

Pseudoephedrine HCl, USP 30 mg – Nasal Decongestant

\*nonsteroidal anti-inflammatory drug



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

**40 Coated Caplets\*\***

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**Questions?** call 1-800-406-7984

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**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)**



5184317



5184317

Non Varnish Area

Expiration Date:

Batch No.

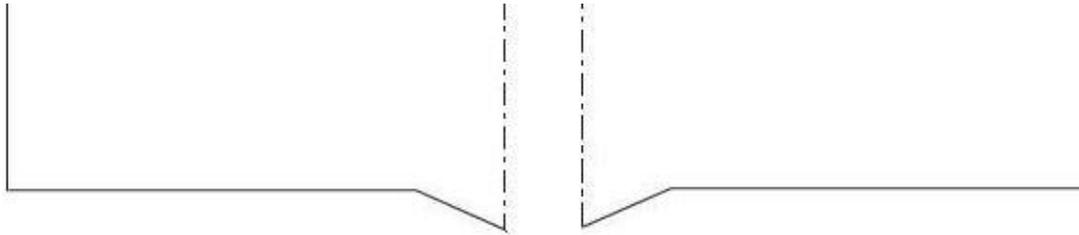
**TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**

<sup>1</sup>All trademarks are property of their respective owners.  
This product is not affiliated with the makers/owners of  
Advil<sup>®</sup> Cold & Sinus.

R0518

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





## IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE

ibuprofen and pseudoephedrine hydrochloride tablet, sugar coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51660-493
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>HYDROXYPROPYL CELLULOSE (1200000 MW)</b> (UNII: RFW2ET671P)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>CROSPVIDONE (15 MPAS AT 5%)</b> (UNII: 68401960MK)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	
<b>GUAR GUM</b> (UNII: E89I1637KE)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

CORN OIL (UNII: 8470G57WFM)

### Product Characteristics

<b>Color</b>	brown	<b>Score</b>	no score
<b>Shape</b>	OVAL (caplets)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	423
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-493-41	40 in 1 BLISTER PACK; Type 0: Not a Combination Product	10/13/2001	

### 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(51660-493)

Revised: 5/2018

Ohm Laboratories Inc.