

**IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE- ibuprofen and pseudoephedrine hydrochloride tablet, sugar coated HEB**

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**H-E-B® Cold & Sinus Relief**

***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**

**PRINCIPAL DISPLAY PANEL - 40 Caplet Blister Pack Carton**

†*Compare to Advil® Cold & Sinus* active ingredients

NDC 37808-423-40

**H-E-B®**

**Cold & Sinus Relief**

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

**Pseudoephedrine HCl, USP 30 mg / Nasal Decongestant**

**Cold & Sinus** \*nonsteroidal anti-inflammatory drug

Non-Drowsy

**Relief of:**

- **Fever • Sinus Pressure**
- **Nasal Congestion**

**40 COATED CAPLETS\*\***

(\*\*oval-shaped tablets)

actual  
size

<p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>Take with food or milk if stomach upset occurs</li> <li>Do not use more than 6 caplets in any 24-hour period unless directed by a doctor</li> <li>Children under 12 years of age: do not use</li> </ul> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>Do not take more than directed</li> <li>The smallest effective dose should be used</li> <li>Adults and children 12 years of age and over:             <ul style="list-style-type: none"> <li>Take 1 caplet every 4 to 6 hours while symptoms persist.</li> <li>Symptoms do not respond to 1 caplet, 2 caplets may be used.</li> </ul> </li> <li>Do not use more than 6 caplets in any 24-hour period unless directed by a doctor</li> <li>Children under 12 years of age: do not use</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if:</b></p> <ul style="list-style-type: none"> <li>You experience any of the following signs of stomach bleeding:             <ul style="list-style-type: none"> <li>● vomit blood</li> <li>● have bloody or black stools</li> <li>● have stomach pain that does not get better</li> </ul> </li> <li>You have symptoms of heart problems or stroke:             <ul style="list-style-type: none"> <li>● chest pain</li> <li>● trouble breathing</li> <li>● weakness in one part of body</li> <li>● slurred speech</li> <li>● leg swelling</li> <li>● liver gets worse or lasts more than 3 days</li> <li>● nasal congestion lasts for more than 7 days</li> <li>● symptoms continue or get worse</li> <li>● redness or swelling is present in the painful area</li> <li>● you get nervous, dizzy, or sleepless</li> <li>● any new symptoms appear</li> </ul> </li> <li>If pregnant or breastfeeding, 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.</li> <li>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)</li> </ul>
<p><b>Drug Facts (continued)</b></p> <p><b>Heart attack and stroke warning:</b> 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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>In children under 12 years of age</li> <li>If you have ever had an allergic reaction to any other pain reliever/fever reducer</li> <li>Right before or after heart surgery</li> <li>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.</li> </ul> <p><b>Ask a doctor before use if you are</b></p> <ul style="list-style-type: none"> <li>Stomach bleeding warning applies to you</li> <li>You have problems or serious side effects from taking pain relievers or fever reducers</li> <li>You have a history of stomach problems, such as heartburn</li> <li>You have high blood pressure, heart disease, liver trouble, kidney disease, asthma, thyroid disease, diabetes, have trouble urinating due to an enlarged prostate gland, or had a stroke</li> <li>You are taking a diuretic</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>Under a doctor's care for any serious condition</li> <li>Taking any other product that contains pseudoephedrine or any other nasal decongestant</li> <li>Taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin</li> <li>Taking any other drug</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>Take with food or milk if stomach upset occurs</li> <li>Do not use more than 6 caplets in any 24-hour period unless directed by a doctor</li> <li>Children under 12 years of age: do not use</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Heart attack and stroke warning:</b> 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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>In children under 12 years of age</li> <li>If you have ever had an allergic reaction to any other pain reliever/fever reducer</li> <li>Right before or after heart surgery</li> <li>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.</li> </ul> <p><b>Ask a doctor before use if you are</b></p> <ul style="list-style-type: none"> <li>Stomach bleeding warning applies to you</li> <li>You have problems or serious side effects from taking pain relievers or fever reducers</li> <li>You have a history of stomach problems, such as heartburn</li> <li>You have high blood pressure, heart disease, liver trouble, kidney disease, asthma, thyroid disease, diabetes, have trouble urinating due to an enlarged prostate gland, or had a stroke</li> <li>You are taking a diuretic</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>Under a doctor's care for any serious condition</li> <li>Taking any other product that contains pseudoephedrine or any other nasal decongestant</li> <li>Taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin</li> <li>Taking any other drug</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>Take with food or milk if stomach upset occurs</li> <li>Do not use more than 6 caplets in any 24-hour period unless directed by a doctor</li> <li>Children under 12 years of age: do not use</li> </ul>

<p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>● Allergic alert: Ibuprofen may cause a severe allergic reaction.</li> <li>● nasal congestion</li> <li>● liver</li> <li>● sinus pressure</li> <li>● minor body aches and pains</li> </ul> <p><b>Uses temporarily relieves these symptoms associated with the common cold or flu:</b></p> <ul style="list-style-type: none"> <li>● headache</li> <li>● fever</li> <li>● sinus pressure</li> <li>● minor body aches and pains</li> </ul> <p><b>Active ingredients (in each caplet) Purposes</b></p> <p>Ibuprofen, USP 200 mg (NSAID).....Pain reliever/fever reducer  Pseudoephedrine HCl, USP 30 mg.....Nasal decongestant  nonsteroidal anti-inflammatory drug</p> <p><b>Stomach bleeding warning:</b> This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you are age 65 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), have 3 or more alcoholic drinks every day while using this product, take more or for a longer time than directed.</p> <p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if:</b></p> <ul style="list-style-type: none"> <li>You experience any of the following signs of stomach bleeding:             <ul style="list-style-type: none"> <li>● vomit blood</li> <li>● have bloody or black stools</li> <li>● have stomach pain that does not get better</li> </ul> </li> <li>You have symptoms of heart problems or stroke:             <ul style="list-style-type: none"> <li>● chest pain</li> <li>● trouble breathing</li> <li>● weakness in one part of body</li> <li>● slurred speech</li> <li>● leg swelling</li> <li>● liver gets worse or lasts more than 3 days</li> <li>● nasal congestion lasts for more than 7 days</li> <li>● symptoms continue or get worse</li> <li>● redness or swelling is present in the painful area</li> <li>● you get nervous, dizzy, or sleepless</li> <li>● any new symptoms appear</li> </ul> </li> <li>If pregnant or breastfeeding, 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.</li> <li>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)</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if:</b></p> <ul style="list-style-type: none"> <li>You experience any of the following signs of stomach bleeding:             <ul style="list-style-type: none"> <li>● vomit blood</li> <li>● have bloody or black stools</li> <li>● have stomach pain that does not get better</li> </ul> </li> <li>You have symptoms of heart problems or stroke:             <ul style="list-style-type: none"> <li>● chest pain</li> <li>● trouble breathing</li> <li>● weakness in one part of body</li> <li>● slurred speech</li> <li>● leg swelling</li> <li>● liver gets worse or lasts more than 3 days</li> <li>● nasal congestion lasts for more than 7 days</li> <li>● symptoms continue or get worse</li> <li>● redness or swelling is present in the painful area</li> <li>● you get nervous, dizzy, or sleepless</li> <li>● any new symptoms appear</li> </ul> </li> <li>If pregnant or breastfeeding, 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.</li> <li>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)</li> </ul>
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\*Compare to Advil® Cold & Sinus active ingredients



NDC 37808-423-40

# Cold & Sinus Relief

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

**Cold & Sinus** \*nonsteroidal anti-inflammatory drug

Non-Drowsy

Relief of:

- Fever • Sinus Pressure
- Nasal Congestion



40 COATED CAPLETS\*\*  
(\*\* oval-shaped tablets)

a actual size

Questions? Call 1-800-467-7561  
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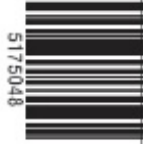
**Drug Facts (continued)**

**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 cap on.

**Inactive Ingredients**

Aluminum Lake, FD&C Red no. 40 Aluminum Lake, FD&C Yellow no. 6 Aluminum Lake, FD&C Yellow no. 5 Aluminum Lake, FD&C Blue no. 2  
acacia, calcium carbonate, carnauba wax, confectioner's sugar, corn starch, croscarmellose sodium, croscopolone, FD&C Blue no. 2



5175048



5175048

Non Varnish Area

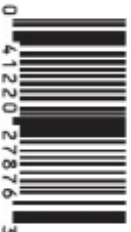
Expiration Date:

Batch No.

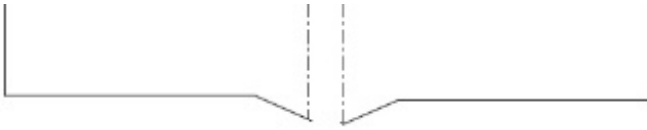
**DAMAGED? DO NOT USE! IF BUSTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF DAMAGE, DO NOT USE! IF BUSTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF DAMAGE, DO NOT USE!**

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This product is not affiliated with the makers/owners of  
Advil® Cold & Sinus.

MADE WITH PRIDE & CARE FOR H-E-B®  
SAY ANTONIO, TX 78204



8649-1802



# 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:37808-423
<b>Route of Administration</b>	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 (15 MPAS AT 5%) (UNII: 68401960MK)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GUAR GUM (UNII: E891I637KE)	
GLYCERYL TRISTEARATE (UNII: P6OCJ2551R)	
HYDROXYPROPYL CELLULOSE (120000 MW) (UNII: RFW2ET671P)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
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)	

## 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:37808-423-40	40 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/17/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074567	04/17/2018	

**Labeler** - HEB (007924756)

**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)

## Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(37808-423)

Revised: 4/2018

HEB