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

H-E-B_® Cold & Sinus Relief

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

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

Cold & Sinus Relief

Ibuprofen, USP 200 mg / Pain Reliver/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)

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Drug Facts (continued)

*Compare to Advil® Cold & Sinus active Ingredients

NDC 37808-423-40



Cold & Sinus Relief

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Cold & Sinus Inonsteroidal anti-inflammatory drug

Non-Drowsy

Relief of:

- Fever Sinus Pressure
- Nasal Congestion

40 COATED CAPLETS**

(**oval-shaped tablets)

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store at 20 - 25 ° C (88 - 77 ° F). Avoid excessive heat above 40 ° C (104 ° F).

In read all warnings and disodors before use. Keep centon. Drug Facts (continued) TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING. All trademarks are properly of their respective owners. This product is not affiliated with the makers/owners of AdvII[®] Cold & Sinus. MADE WITH PRIDE & CARE FOR H-E-B[®] SAN ANTONIO, TX 78204 Expiration Date: Non Varnish Area Batch No.

IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE

ibuprofen and pseudoephedrine hydrochloride tablet, sugar coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-423	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	200 mg	
PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9 F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg	

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
CROSPOVIDONE (15 MPA.S 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: E8911637KE)	
GLYCERYL TRISTEARATE (UNII: P6 O CJ2551R)	
HYDROXYPROPYL CELLULOSE (1200000 MW) (UNII: RFW2ET671P)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PO WDERED CELLULO SE (UNII: SMD1X3XO9 M)	
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	

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

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ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		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