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

Ibuprofen and Pseudoephedrine Hydrochloride

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 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 **1-888-723-3929**

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PRINCIPAL DISPLAY PANEL - 40 Tablet Blister Pack Carton

NDC 21130-423-41

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care™

Quality Guaranteed

SEE NEW WARNINGS INFORMATION
Cold & Sinus
Relief
Ibuprofen and Pseudoephedrine
HCl Tablets, USP

Actual Size

Compare to
Advil®
Cold & Sinus

active ingredients†

- Ibuprofen, USP 200 mg
  pain reliever/fever reducer (NSAID)*
- Pseudoephedrine HCl, USP 30 mg
  nasal decongestant
- Non-drowsy
  Relieves sinus pressure, nasal congestion and fever

*nonsteroidal anti-inflammatory drug

40 COATED CAPLETS (**OVAL-SHAPED TABLETS)**

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NDC 21130-423-41

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SEE NEW WARNINGS INFORMATION

Cold & Sinus Relief

Ibuprofen and Pseudoephedrine HCl Tablets, USP

Actual Size

Compare to Advil® Cold & Sinus active ingredients†

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Questions? call 1-888-723-3929

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s product is not affiliated with the makers/owners of
il® Cold & Sinus.

Batch No.

Expiration Date:

Non Varnish Area

TAMPER EVIDENT: DO NOT USE IF BLISTER U
TORN, BROKEN OR SHOW ANY SIGNS OF TAM

R0518

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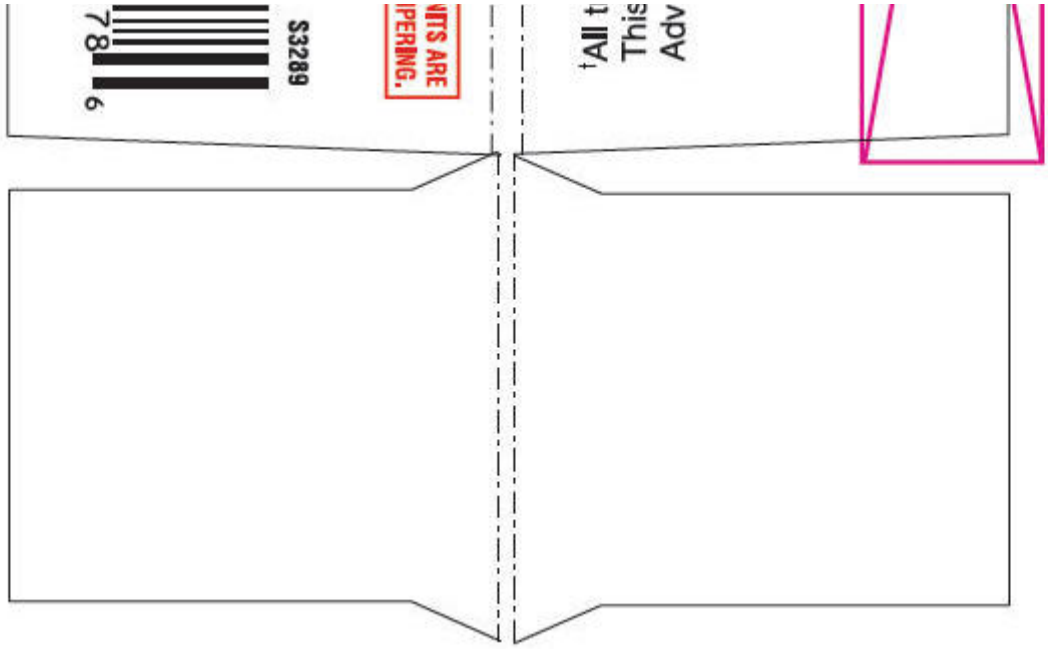

IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE

ibuprofen and pseudoephedrine hydrochloride tablet, sugar coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21130-423
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
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: E89I1637KE)	
GLYCERYL TRISTEARATE (UNII: P6OCJ2551R)	
HYDROXYPROPYL CELLULOSE (1200000 MW) (UNII: RFW2ET671P)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

KAOLIN (UNII: 24H4NWX5CO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, 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:21130-423-41	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 - Safeway Inc. (009137209)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(21130-423)

Revised: 5/2018 Safeway Inc.