

**GOOD NEIGHBOR PHARMACY IBUPROFEN COLD AND SINUS- ibuprofen,
pseudoephedrine hydrochloride tablet
Dispensing Solutions, Inc.**

Amerisource Bergen Ibuprofen Cold and Sinus Drug Facts

Active ingredient (in each caplet)

Ibuprofen, USP 200 mg (NSAID)*

Pseudoephedrine HCl, USP 30 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Nasal decongestant

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

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 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 20-25°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, FD&C red no. 40, FD&C yellow no. 6, gelatin, guar gum, hydrogenated vegetable oil, hydroxypropyl cellulose, kaolin, pharmaceutical ink, polyethylene glycol, powdered cellulose, povidone, pregelatinized starch, silicon dioxide, sodium benzoate, sucrose, talc, titanium dioxide, white wax

Questions or comments?

1-800-719-9260

Principal Display Panel

COMPARE TO ACTIVE INGREDIENTS IN ADVIL® COLD & SINUS

Non Drowsy

Ibuprofen Cold & Sinus

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

Pseudoephedrine HCl 30 mg – Nasal Decongestant

Tablets, USP

*nonsteroidal anti-inflammatory drug

Relieves Sinus Pressure, Nasal Congestion and Fever

See New Warnings Information

**OVAL-SHAPED TABLETS

NDC 68258-8902-02

BULK SOURCE DATA

DIST. BY: AMERISOURCEBERGEN
CHESTERBROOK, PA 19087

PRODUCT ID:

WHITE / BLUE / LIGHT BLUE / RED /
YELLOW / DARK RASPBERRY / PINK /
LIGHT BROWN / BROWN / BLACK
BOX PRINTED NDC 24385-465-60

BULK SOURCE NDC: 24385-0465-60

MFR. LOT: XXXXXX

PEDIGREE #: 712810569

DISPENSE IN THIS

TIGHT/LIGHT RESISTANT CONTAINER



TAKE ___ CAPLET(S)
ORALLY EVERY ___ HOURS
___ TIMES A DAY. DO NOT
USE MORE THAN 6 CAPLETS
IN ANY 24-HOUR PERIOD
UNLESS DIRECTED BY A
DOCTOR. TAKE WITH FOOD.
AVOID ALCOHOL.



IBUPROFEN/PSE HCl COLD&SINUS

(NON-DROWSY)

20 (200 mg/30 mg) CAPLETS

NDC 68258-8902-02

PRODUCT # 810220

Rev. Date: 05/13

ACTIVE INGREDIENT (IN EACH COATED CAPLET):

IBUPROFEN USP 200 mg

(PURPOSE: PAIN RELIEVER/FEVER REDUCER)

PSEUDOEPHEDRINE HYDROCHLORIDE USP 30 mg

(PURPOSE: NASAL DECONGESTANT)

FD&C YELLOW No. 6

SEE BOX FOR WARNINGS INFORMATION.

COMPARE TO ACTIVE INGREDIENTS IN ADVIL® COLD & SINUS CAPLETS

LOT#SAMPLE EXP: 00-00 Rx # 32692018

WARNING: KEEP OUT OF
CHILDREN'S REACH
STORE AT 68° - 77° F. SEE USP.

810220 NDC 68258-8902-02
IBUPROFEN/PSE HCl COLD&SINUS
20 (200 mg/30 mg) CAPLETS
LOT # SAMPLE EXP: 00-00
MN 24385-0465-60 RX# 32692018

810220 NDC 68258-8902-02
IBUPROFEN/PSE HCl COLD&SINUS
20 (200 mg/30 mg) CAPLETS
LOT # SAMPLE EXP: 00-00
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810220 NDC 68258-8902-02
IBUPROFEN/PSE HCl COLD&SINUS
20 (200 mg/30 mg) CAPLETS
LOT # SAMPLE EXP: 00-00
MN 24385-0465-60 RX# 32692018



Packaged Exclusively By:
DISPENSING SOLUTIONS
Santa Ana, CA 92704

GOOD NEIGHBOR PHARMACY IBUPROFEN COLD AND SINUS

ibuprofen, pseudoephedrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68258-8902(NDC:24385-465)
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)	
SUCROSE (UNII: C151H8M554)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 68401960MK)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GUAR GUM (UNII: E891I637KE)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
KAOLIN (UNII: 24H4NWX5CO)	

POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	BROWN	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	083
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68258-8902-2	2 in 1 CARTON		
1		10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074567	10/15/2001	

Labeler - Dispensing Solutions, Inc. (066070785)

Registrant - PSS World Medical, Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel(68258-8902) , repack(68258-8902)

Revised: 6/2013

Dispensing Solutions, Inc.