SINUS CONGESTION AND PAIN- ibuprofen, phenylephrine hydrochloride tablet, film coated
Rite Aid Corporation

Rite Aid Corporation Sinus Congestion & Pain Drug Facts

Active ingredients (in each tablet)

Ibuprofen 200 mg (NSAID)*

Phenylephrine HCl 10 mg

*nonsteroidal anti-inflammatory drug

Purposes

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
- reduces swelling of the nasal passages
- temporarily restores freer breathing through the nose

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 because this product contains too much medication for children under this 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 phenylephrine 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
- pain gets worse or lasts more than 7 days
- 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**
- adults and children 12 years of age and over:
- take 1 tablet every 4 hours while symptoms persist.
- do not use more than 6 tablets in any 24-hour period unless directed by a doctor
- children under 12 years of age: do not use because this product contains too much medication for children under this age

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

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, FD&C

blue #2 aluminum lake, FD&C yellow #6 aluminum lake, iron oxide yellow, lactose

monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

FREE FROM | GLUTEN FREE

Compare to the active ingredients of Advil® Sinus Congestion & Pain

NON-DROWSY

SINUS CONGESTION & PAIN

IBUPROFEN 200 mg/PHENYLEPHRINE HYDROCHLORIDE 10 mg TABLETS

PAIN RELIEVER/FEVER REDUCER (NASAID) & NASAL DECONGESTANT

ACTUAL SIZE

Relief of: nasal congestion, headache, sinus pressure, fever, nasal swelling, body aches

20 COATED TABLETS

15680 83 C1

NDC 11822-5158-0

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DISTRIBUTED BY: RITE AID
200 NEUBERRY COMMONS
ETTERS, PA 17319
www.riteaid.com

SATISFACTION GUARANTEE
If you're not satisfied, we'll happily refund your money.

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

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Drug Facts (continued)

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Do not use
- in children under 12 years of age because this product contains too much medication for children under this 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

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Questions or comments? 1-800-719-9260

**This product is not manufactured or distributed by Pfizer Inc., distributor of Advil® Sinus Congestion & Pain.

SINUS CONGESTION AND PAIN

ibuprofen, phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11822-5158
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN (brownish-orange)	**Score**	no score
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	L158
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-5158-0	20 in 1 CARTON	07/19/2023	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203200	07/19/2023	

Labeler - Rite Aid Corporation (014578892)

Revised: 7/2023 Rite Aid Corporation