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

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## 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** 

GLUTEN FREE FREE FREM

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

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ACTUAL SIZE

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# COATED TABLET

#### DO NOTUSE IF BLISTER UNIT IS BROKEN OR TORN

READAND KEEP CARTON FOR COMPILETE WARNINGS AND INFORMATION

#### Drug Facts

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Questions or comments?1-800-7194260

\*\*\*This product is not manufactured or distributed by Pifter Inc., distributor of Advillo Sinus Concesion & Pain.



DISTRIBUTED BY: RITE AID 200 NEWBERRY COMMONS ETTERS, PA 17319

## **SINUS CONGESTION AND PAIN**

ibuprofen, phenylephrine hydrochloride tablet, film coated

<b>Product</b>	Intorm	ation

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: 230V73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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			

F	Packaging			
#	tem 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