

**ADVIL SINUS CONGESTION AND PAIN RELIEF- ibuprofen, phenylephrine hydrochloride tablet, coated**  
**Navajo Manufacturing Company Inc.**

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**Advil Sinus Congestion & Pain Relief**

***Drug Facts***

***Active ingredient (in each tablet)***

Ibuprofen 200 mg (NSAID)\*

Phenylephrine HCl 10 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 • 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 • rash • skin reddening • 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***

- 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 or have 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 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
- 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

- 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.

## 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, artificial flavor, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, glycerin, hypromellose, lactic acid, lecithin, maltodextrin, medium-chain triglycerides, microcrystalline cellulose, pharmaceutical ink, polydextrose, polyvinyl alcohol, pregelatinized starch, propyl gallate, sodium lauryl sulfate, stearic acid, sucralose, synthetic iron oxide, talc, titanium dioxide, triacetin, xanthan gum

## Questions or comments?

Call weekdays from 9 AM to 5 PM EST toll free at 1-800-88-ADVIL

## Package Labeling:



## ADVIL SINUS CONGESTION AND PAIN RELIEF

ibuprofen, phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-150(NDC:0573-0199)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LACTIC ACID</b> (UNII: 33X04XA5AT)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

Product Characteristics			
Color	brown (tan)	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	1200;P10
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-150-	1 is 1 CARTON	08/28/2016	

1	01	1 in 1 CARTON	09/20/2016	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67751-150-02	1 in 1 CARTON	09/20/2016	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA		NDA022565	09/20/2016	

**Labeler -** Navajo Manufacturing Company Inc. (091917799)

## Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-150) , repack(67751-150)

Revised: 3/2023

Navajo Manufacturing Company Inc.