ADVIL ALLERGY AND CONGESTION RELIEF- chlorpheniramine maleate, ibuprofen, phenylephrine hydrochloride tablet, coated
Navajo Manufacturing Company Inc.

Advil Allergy & Congestion Relief

Drug Facts

Active ingredients (in each tablet)

Chlorpheniramine Maleate 4 mg

Ibuprofen 200 mg (NSAID)*

Phenylephrine HCl 10 mg

*nonsteroidal anti-inflammatory drug

Purposes

Antihistamine

Pain reliever/Fever reducer

Nasal decongestant

Uses

• temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:
• runny nose • itchy, watery eyes • itching of the nose or throat
• sneezing • nasal congestion • sinus pressure
• headache • fever • 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

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

• you have a breathing problem such as emphysema or chronic bronchitis
• 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, glaucoma 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 sedatives or tranquilizers
• taking any other product that contains phenylephrine, chlorpheniramine or any other nasal decongestant or antihistamine
• 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 • avoid alcoholic drinks
• be careful when driving a motor vehicle or operating machinery
• drowsiness may occur
• alcohol, sedatives, and tranquilizers may increase drowsiness
• may cause excitability especially in children

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 • redness or swelling is present in the painful area • you get nervous, dizzy, or sleepless • symptoms continue or get

worse
• 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

• read all warnings and directions before use. Keep Carton.
• store at 20-25°C (68-77°F) • avoid excessive heat above 40°C (104°F)

Inactive ingredients

acesulfame potassium, artificial flavors, carnauba wax, colloidal silicon dioxide, corn starch, croscarmellose sodium, glycerin, glyceryl behenate, hypromellose, lactic acid, lecithin, maltodextrin, medium-chain triglycerides, microcrystalline cellulose, pharmaceutical ink, polydextrose, polyvinyl alcohol, pregelatinized starch, propyl gallate, silicon dioxide, 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 ALLERGY AND CONGESTION RELIEF

chlorpheniramine maleate, ibuprofen, phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67751-149(NDC:0573-0196)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg
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)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTIC ACID (UNII: 33X04XA5AT)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

PROPYL GALLATE (UNII: 8D4SNN7V92)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	gray	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	Advil;A;CR
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67751-149-01	1 in 1 CARTON	09/16/2016	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67751-149-02	2 in 1 CARTON	09/16/2016	
2		1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:67751-149-03	12 in 1 TRAY	09/16/2016	01/01/2021
3		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022113	09/16/2016	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment

Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-149) , repack(67751-149)

Revised: 3/2023 Navajo Manufacturing Company Inc.