

ADVIL ALLERGY AND CONGESTION RELIEF- chlorpheniramine maleate, ibuprofen, and phenylephrine hydrochloride tablet, coated
Haleon US Holdings LLC

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
 - minor body aches and pains
 - fever
- 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

- 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, 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 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
- 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
- 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
- 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 at 20 weeks or later in 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 take 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 dibehenate, 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**

Additional Information

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Product inside sealed in plastic blister with foil backing.
Do Not Use if plastic blister or foil barrier is broken.

Distributed by: GSK Consumer Healthcare, Warren, NJ 07059

For most recent product information,
visit www.advil.com

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PRINCIPAL DISPLAY PANEL

Advil

ALLERGY & CONGESTION RELIEF

Chlorpheniramine Maleate 4 mg Antihistamine
Ibuprofen 200 mg Pain Reliever/Fever Reducer (NSAID)
Phenylephrine HCl 10 mg Nasal Decongestant

- **Sneezing**
- **Nasal Congestion**
- **Sinus Pressure**
- **Nasal Swelling**
- **Runny Nose**
- **Headache**
- **Fever**
- **Body Aches**

Advil

A&CR

**ONE
PILL
DOSE!**

10 Coated Tablets

PAA147206 Carton Front



PRINCIPAL DISPLAY PANEL

Advil

**ALLERGY &
CONGESTION RELIEF**

**Chlorpheniramine Maleate 4 mg Antihistamine
Ibuprofen 200 mg Pain Reliever/Fever Reducer (NSAID)
Phenylephrine HCl 10 mg Nasal Decongestant**

**50%
MORE**

10 FREE

Tablets

- Sneezing
- Nasal Congestion
- Sinus Pressure
- Nasal Swelling
- Runny Nose
- Headache
- Fever
- Body Aches
- Advil

Advil

A&CR

ONE

TABLET

DOSE!

30 Coated Tablets

000066065 Carton Front



ADVIL ALLERGY AND CONGESTION RELIEF

chlorpheniramine maleate, ibuprofen, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

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, UNSPECIFIED FORM (UNII: 33X04XA5AT)				
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)				
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)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
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:0573-0196-01	50 in 1 TRAY	07/23/2012	

1		1 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0573-0196-10	1 in 1 CARTON	07/23/2012	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0573-0196-20	2 in 1 CARTON	07/23/2012	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0573-0196-02	2 in 1 CARTON	10/01/2019	
4		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022113	07/23/2012	

ADVIL ALLERGY AND CONGESTION RELIEF

chlorpheniramine maleate, ibuprofen, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-2161
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, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
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)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
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:0573-2161-03	2 in 1 CARTON	10/01/2019	
1		10 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
NDA	NDA022113	07/23/2012	

Labeler - Haleon US Holdings LLC (079944263)