ADVIL ALLERGY AND CONGESTION RELIEF - chlorpheniramine maleate, ibuprofen, and phenylephrine hydrochloride tablet, coated
Pfizer Consumer Healthcare

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Advil®
ALLERGY & CONGESTION RELIEF

Drug Facts

<table>
<thead>
<tr>
<th>Active ingredients (in each tablet)</th>
<th>Purposes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorpheniramine maleate 4 mg</td>
<td>Antihistamine</td>
</tr>
<tr>
<td>Ibuprofen 200 mg (NSAID)*</td>
<td>Pain reliever/Fever reducer</td>
</tr>
<tr>
<td>Phenylephrine HCl 10 mg</td>
<td>Nasal decongestant</td>
</tr>
</tbody>
</table>

* nonsteroidal anti-inflammatory drug

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
- asthma (wheezing)
- skin reddening
- blisters
- facial swelling
- shock
- rash

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 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 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, glycercyl 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
PRINCIPAL DISPLAY PANEL - 1 Tablet Packet

Advil®
ALLERGY & CONGESTION RELIEF

Chlorpheniramine Maleate 4 mg
Antihistamine
Ibuprofen 200 mg (NSAID)*
Pain reliever/Fever reducer
Phenylephrine HCl 10 mg
Nasal decongestant

1 Tablet
*nonsteroidal anti-inflammatory drug
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.
PRINCIPAL DISPLAY PANEL - 50 Packet Tray

Advil®
ALLERGY & CONGESTION RELIEF
Chlorpheniramine Maleate 4 mg Antihistamine
Ibuprofen 200 mg Pain Reliever/Fever Reducer (NSAID)
Phenylephrine HCl 10 mg Nasal Decongestant

1
PILL
DOSAGE
Advil
A&CR
Relief of: Sinus Pressure, Nasal Swelling & Congestion, Sneezing, Runny Nose and Headache

50 PACKETS OF 1 COATED TABLET
PRINCIPAL DISPLAY PANEL - 10 Tablet Blister Pack Carton

Advil®

ALLERGY &
CONGESTION RELIEF

Chlorpheniramine Maleate 4 mg Antihistamine
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Advil
A&CR

ONE
PILL
DOSE!

10
Coated
Tablets
- Sneezing
- Nasal Congestion
- Sinus Pressure
- Nasal Swelling
- Runny Nose
- Headache
- Fever
- Body Aches
**Drug Facts**

**Active ingredients (in each tablet)**
- Chlorpheniramine maleate 4 mg — Antihistamine
- Ibuprofen 200 mg (NSAID) — Pain reliever, Fever reducer
- Phenylephrine HCl 10 mg — Nasal decongestant
- *nonsteroidal anti-inflammatory drug*

**Uses**
- temporarily relieves symptoms associated with hay fever or other upper respiratory allergies and the common cold:
  - itchy, watery eyes
  - itching of the nose or throat
  - sneezing
  - runny nose
  - nasal congestion
  - sinus pressure
  - urinating body aches and pains
  - fever
  - reduces swelling of the nasal passages
  - temporarily restores freer breathing through the nose

**Drug Facts (continued)**

**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
  - Blisters
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**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
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  - 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
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- If you have ever had an allergic reaction to any other pain reliever/fever reducer
- Right before or after heart surgery
- If you are 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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- You are taking a diuretic

**Ask a doctor or pharmacist before use if you are**
- Under a doctor's care for any serious condition
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- 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

**Drug Facts (continued)**
### ADVIL ALLERGY AND CONGESTION RELIEF
chlorpheniramine maleate, ibuprofen, and phenylephrine hydrochloride tablet, coated

#### Product Information

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<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
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<td>Route of Administration</td>
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#### Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z)</td>
<td>CHLORPHENIRAMINE MALEATE</td>
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<td>IBUPROFEN (UNII: WK2XY110QMJ)</td>
<td>IBUPROFEN</td>
<td>200 mg</td>
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<td>PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ)</td>
<td>PHENYLEPHRINE HYDROCHLORIDE</td>
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#### Inactive Ingredients

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<tr>
<th>Ingredient Name</th>
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<tr>
<td>ACESULFAME POTASSIUM (UNII: 230V73Q5G9)</td>
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<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
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<td>GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)</td>
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<td>HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)</td>
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EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9HE2L21V7U)
MICROCRYSTALLINE CELLULOSE (UNII: OPIR32D61U)
POLYDEXTOSE (UNII: VH2XOU12IE)
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)
PROPYLE 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

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<tr>
<th>Color</th>
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<tr>
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Packaging

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<tr>
<th>#</th>
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<th>Package Description</th>
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<th>Marketing End Date</th>
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Marketing Information

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<td>NDA</td>
<td>NDA022113</td>
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Labeler - Pfizer Consumer Healthcare (828831730)

Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
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<th>Business Operations</th>
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<tbody>
<tr>
<td>Wyeth Pharmaceuticals Company</td>
<td>829390975</td>
<td>ANALYSIS(0573-0196) , LABEL(0573-0196) , MANUFACTURE(0573-0196) , PACK(0573-0196)</td>
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