CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride solution
Preferred Pharmaceuticals Inc.

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Cetirizine Hydrochloride Oral Solution - Allergy

Drug Facts

Active ingredient (in each 5 mL (teaspoonful(tsp)): Cetirizine HCl 5 mg

Purpose: Antihistamine

Uses
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

• runny nose
• itchy, watery eyes
• sneezing
• itching of the nose or throat

Warnings

Do not use
if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine

Ask a doctor before use if you have
liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are
taking tranquilizers or sedatives.

When using this product

• drowsiness may occur
• avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding

• If breast-feeding: not recommended
• if pregnant: ask a health professional before use.

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**

use only with enclosed dosing cup

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>adults and children 6 years and over</td>
<td>1 teaspoonful (tsp)(5 mL) or 2 teaspoonfuls (tsp)(10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (tsp)(10 mL) in 24 hours.</td>
</tr>
<tr>
<td>adults 65 years and over</td>
<td>1 teaspoonful (tsp)(5 mL) once daily; do not take more than 1 teaspoonful (tsp)(5 mL) in 24 hours.</td>
</tr>
<tr>
<td>children 2 to under 6 years of age</td>
<td>1/2 teaspoonful (tsp)(2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (tsp)(5 mL) once daily or 1/2 teaspoonful (tsp)(2.5 mL) every 12 hours. Do not give more than 1 teaspoonful (tsp)(5 mL) in 24 hours.</td>
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<tr>
<td>children under 2 years of age</td>
<td>ask a doctor</td>
</tr>
<tr>
<td>consumers with liver or kidney disease</td>
<td>ask a doctor</td>
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</tbody>
</table>

**Other information**

Store between 20º to 25ºC (68º to 77ºF)

**Inactive ingredients**

calcium acetate, grape flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water.

**Questions?**

Call 1-888-974-5279

**Cetirizine Hydrochloride Oral Solution - Hives Relief**

**Drug Facts**

**Active ingredient (in each 5 mL (teaspoonful)):** Cetirizine HCl 5 mg

**Purpose:** Antihistamine

**Uses**

relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

**Warnings**

**Severe Allergy Warning:** Get emergency help immediately if you have hives along with any of the following symptoms:

- trouble swallowing
- dizziness or loss of consciousness
These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by health professional immediately. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

**Not a Substitute for Epinephrine.** If your doctor has prescribed an epinephrine injector for “anaphylaxis” or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

**Do not use**

- to prevent hives from any known cause such as:
  - foods
  - insect stings
  - medicines
  - latex or rubber gloves because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.
  - if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

**Ask a doctor before use if you have**

- liver or kidney disease. Your doctor should determine if you need a different dose
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

**Ask a doctor or pharmacist before use if you are**

taking tranquilizers or sedatives

**When using this product**

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if**

- an allergic reaction to this product occurs. Seek medical help right away.
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

**If pregnant or breast-feeding**
• If breast-feeding: not recommended
• if pregnant: ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
use only with enclosed dosing cup

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Other information
Store between 20º to 25ºC (68º to 77ºF)

Inactive ingredients
calcium acetate, grape flavor, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water

Questions?
Call 1-888-974-5279

Dosing Cup Included
Dosing cup should be washed and left to air dry after each use.

Do not use if carton is open; or if safety seal printed with “SEALED FOR YOUR PROTECTION” around cap of the bottle is broken or missing.

SAVE THIS CARTON FOR FULL LABELING INFORMATION

Relabeled By: Preferred Pharmaceuticals Inc.
NDC 68788-7585-1
Relabeled By: Preferred Pharmaceuticals Inc.
NDC 68788-7585-1
CETIRIZINE HYDROCHLORIDE
cetirizine hydrochloride solution

Product Information

Product Type: HUMAN OTC DRUG
Route of Administration: ORAL

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)</td>
<td>CETIRIZINE HYDROCHLORIDE</td>
<td>5 mg in 5 mL</td>
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</table>

Inactive Ingredients

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<tr>
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<th>Strength</th>
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<tbody>
<tr>
<td>CALCIUM ACETATE (UNII: Y882YXF34X)</td>
<td></td>
</tr>
<tr>
<td>ACETIC ACID (UNII: Q40Q9N063P)</td>
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</tr>
<tr>
<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
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<tr>
<td>METHYLPARABEN (UNII: A2B C7H9T)</td>
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</tr>
<tr>
<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
<td></td>
</tr>
<tr>
<td>PROPYL PARABEN (UNII: Z8IX2SC1OH)</td>
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</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
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</tr>
</tbody>
</table>

Product Characteristics

Color: Score
Shape: Size
Flavor: GRAPE (Grape Flavor)
Contains: Imprint Code

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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**Marketing Information**

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<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>ANDA</td>
<td>ANDA091130</td>
<td>02/18/2020</td>
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**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals Inc. (791119022)

**Establishment**

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred Pharmaceuticals Inc.</td>
<td></td>
<td>791119022</td>
<td>RELABEL(68788-7585)</td>
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</tbody>
</table>

Revised: 2/2020

Preferred Pharmaceuticals Inc.