

CETRIZINE HYDROCHLORIDE- cetirizine hydrochloride solution
APOZEAL PHARMACEUTICALS INC

Cetirizine Hydrochloride Oral Solution 1 mg/mL

Drug Facts

Active ingredient (in each 5 mL teaspoonful) Purpose

Cetirizine HCl 5 mg-----Antihistamine

Purpose

Antihistamine

Uses

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

- runny nose
- sneezing
- itchy, watery eyes
- 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
- adults and children 6 years and over: 1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours.
- adults 65 years and over: 1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) in 24 hours.
- children 2 to under 6 years of age: 1/2 teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or 1/2 teaspoonful (2.5 mL) every 12 hours. Do not give more than 1 teaspoonful (5 mL) in 24 hours.
- children under 2 years of age: ask a doctor
- consumers with liver or kidney disease: ask a doctor

Other information

- store between 20° to 25°C (68° to 77°F)
- **Do not use if foil seal over mouth of the bottle is torn, broken or missing.**
- **Gluten Free**
- **Dosing cup should be washed and left to air dry after each use.**

Inactive ingredients

glacial acetic acid, glycerine, grape flavor, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate, sucrose

Questions or comments?

1-833-688-7848

Distributed by:

Apozeal Pharmaceuticals Inc.

Hartel St, Levittown PA 19057

PRINCIPAL DISPLAY PANEL

NDC 83745-188-24

Cetirizine Hydrochloride

Oral Solution 1 mg/mL

Antihistamine

**INDOOR & OUTDOOR
ALLERGIES**

(240 mL)

Grape Flavored Syrup

NDC 83745-188-24

Cetirizine Hydrochloride

Oral Solution, USP

1mg/mL

Antihistamine

INDOOR & OUTDOOR

ALLERGIES

24 HOUR RELIEF OF:

Runny Nose / Itchy, Watery Eyes


Itchy Throat or Nose / Sneezing

8 FL OZ 24 Hour

(240 mL) 2yrs. & older

Dye-Free

Grape Flavored Syrup



Active ingredient (in each 5 mL)

Cetirizine HCl 5 mg.....Antihistamine

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

■ runny nose ■ sneezing ■ itchy, watery eyes

■ itching of the nose or throat

Warnings

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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

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

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Purpose

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Gluten Free

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Rev. 01/2026



MADE IN USA



N 3 83745 18824 1

CETRIZINE HYDROCHLORIDE

cetirizine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83745-188
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CETRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETRIZINE - UNII:YO7261ME24)		CETRIZINE HYDROCHLORIDE	1 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
METHYLPARABEN (UNII: A2I8C7HI9T)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM ACETATE (UNII: 4550K0SC9B)			
GRAPE (UNII: 6X543N684K)			
ACETIC ACID (UNII: Q40Q9N063P)			
SUCROSE (UNII: C151H8M554)			
WATER (UNII: 059QF0KO0R)			
Product Characteristics			

Color	YELLOW (Colorless to slightly yellow)		Score	
Shape			Size	
Flavor	GRAPE		Imprint Code	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83745-188-04	1 in 1 CARTON	01/20/2026	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:83745-188-08	1 in 1 CARTON	01/20/2026	
2		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:83745-188-12	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/20/2026	
4	NDC:83745-188-24	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/20/2026	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090474	01/01/2025	

Labeler - APOZEAL PHARMACEUTICALS INC (119101193)

Registrant - APOZEAL PHARMACEUTICALS INC (119101193)

Establishment			
Name	Address	ID/FEI	Business Operations
APOZEAL PHARMACEUTICALS INC		119101193	MANUFACTURE(83745-188) , ANALYSIS(83745-188) , pack(83745-188)

Revised: 1/2026

APOZEAL PHARMACEUTICALS INC