CETIRIZINE HYDROCHLORIDE (ALLERGY) - cetirizine hydrochloride tablet
CVS Pharmacy, Inc.

Drug Facts

Active ingredient (in each tablet)

Cetirizine hydrochloride USP 10 mg

Purpose

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

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

adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 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)
- **TAMPER EVIDENT: DO NOT USE IF SEAL OVER BOTTLE OPENING IS BROKEN OR MISSING.**

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

Questions?

call **1-855-274-4122**

Distributed by:
CVS Pharmacy, Inc.
One CVS Drive,
Woonsocket, RI 02895

CVS.com®
1-800-SHOP CVS

Made in India

Code: TS/DRUGS/19/1993

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (30 Tablets Container Label)

♥CVS

Health®

NDC 69842-237-09
Indoor & Outdoor
Allergies
Original Prescription Strength
Allergy Relief
CETIRIZINE
HYDROCHLORIDE
TABLETS USP 10 mg
Antihistamine
24 Hour
30 TABLETS

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (30 Tablets Container Carton Label)

♥CVS Health®

Compare to the active

ingredient in Zyrtec® Tablets*

Indoor & Outdoor Allergies
NDC 69842-237-09
Original Prescription Strength
Allergy Relief
CETIRIZINE HYDROCHLORIDE
TABLETS USP 10 mg
Antihistamine
24 Hour

Relief of:

- **Sneezing**
- **Runny nose**
- **Itchy, watery eyes**
- **Itchy throat or nose**

Actual Bottle Size
on Side Panel
Actual Size
30 TABLETS

CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-237
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (White to Off-white)	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	X;36
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-237-91	1 in 1 CARTON	07/26/2019	06/10/2023
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-237-09	1 in 1 CARTON	07/26/2019	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69842-237-17	1 in 1 CARTON	07/26/2019	
3		45 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69842-237-54	1 in 1 CARTON	07/26/2019	01/11/2021
4		70 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69842-237-19	1 in 1 CARTON	07/26/2019	
5		90 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:69842-237-23	1 in 1 CARTON	07/26/2019	
6		120 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:69842-237-45	2 in 1 CARTON	07/26/2019	
7		120 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:69842-237-39	365 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2019	
9	NDC:69842-237-60	1 in 1 CARTON	07/26/2019	01/10/2022
9		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
10	NDC:69842-237-57	1 in 1 CARTON	07/26/2019	01/08/2023
10		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
11	NDC:69842-237-01	1 in 1 CARTON	07/26/2019	
11		14 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
ANDA	ANDA090760	07/26/2019	

Labeler - CVS Pharmacy, Inc. (062312574)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(69842-237) , MANUFACTURE(69842-237)