

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, coated
NCS HealthCare of KY, LLC dba Vanguard Labs

Cetirizine Hydrochloride Tablets

Cetirizine Hydrochloride Tablets

Drug Facts

Active Ingredient (in each tablet)

Cetirizine HCl 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 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)
- contains no ingredient made from a gluten-containing grain (Wheat, barley or rye).

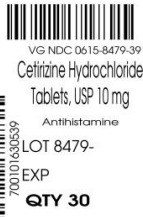
Inactive ingredients

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

QUESTIONS?

call 1-877-770-3183: Mon-Fri 8:00 AM EST to 5:00 PM PST

PRINCIPAL DISPLAY PANEL



(Granules NDC 70010-163-05)
Cetirizine Hydrochloride
Tablets, USP 10 mg

Received: _____
24 _____ 16 _____ 8 _____
31 _____ 23 _____ 15 _____ 7 _____
30 _____ 22 _____ 14 _____ 6 _____
29 _____ 21 _____ 13 _____ 5 _____
28 _____ 20 _____ 12 _____ 4 _____
27 _____ 19 _____ 11 _____ 3 _____
26 _____ 18 _____ 10 _____ 2 _____
25 _____ 17 _____ 9 _____ 1 _____
Start Date _____ Start Time _____

See Bottle Label for Drug Facts
and full labeling information.

Store between 20°-25°C (68°-77°F).

Mfg By Granules (NDC 70010-163-05) PKG BY VANGARD GLASGOW, KY 42141	TAMPER EVIDENT	8479-AA-39 v01	16	8
30	23	15	7	
29	22	14	6	
28	21	13	5	
27	20	12	4	
26	19	11	3	
25	18	10	2	
24	17	9	1	

FOR INSTITUTIONAL USE ONLY

Pkg by Vanguard, Glasgow, KY 42141 Cetirizine Hydrochloride Tablet, USP 10 mg	Pkg by Vanguard, Glasgow, KY 42141 Cetirizine Hydrochloride Tablet, USP 10 mg	Pkg by Vanguard, Glasgow, KY 42141 Cetirizine Hydrochloride Tablet, USP 10 mg	8479-AA-B-v02 Vanguard USA Glasgow, KY 42141
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CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0615-8479(NDC:70010-163)
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
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	

Product Characteristics

Color	white (white to off white)	Score	2 pieces
Shape	RECTANGLE (rounded off rectangular)	Size	9mm
Flavor		Imprint Code	G;4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-8479-39	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/31/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209274	01/13/2022	

Labeler - NCS HealthCare of KY, LLC dba Vanguard Labs (050052943)

Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, LLC dba Vanguard Labs		050052943	repack(0615-8479)

Revised: 6/2024

NCS HealthCare of KY, LLC dba Vanguard Labs