CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Marlex Pharmaceuticals, Inc

Cetirizine Hydrochloride

Drug Facts

Active ingredient (in each tablet)

Cetirizine HCl, 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

- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**
- store between 20° to 25° C (68° to 77° F)

Inactive ingredients

corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide

Manufactured for/ Distributed by:

Marlex Pharmaceuticals, Inc.

New Castle, DE 19720

Rev. 10/22 SP

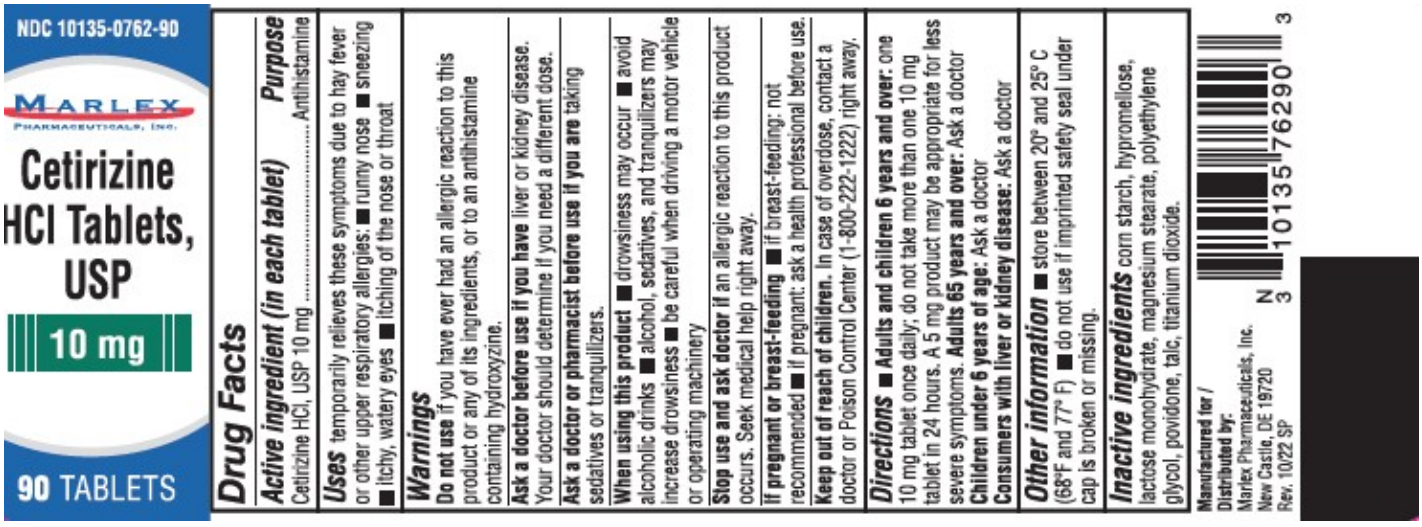
PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label

NDC 10135-0762-30

Allergy Relief
Cetirizine HCl Tablets, USP 10 mg
ANTIHISTAMINE

30 TABLETS

PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label



NDC 10135-0762-90

Allergy Relief
Cetirizine HCl Tablets, USP 10 mg
ANTIHISTAMINE

90 TABLETS

PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label

NDC 10135-0762-01

Allergy Relief
Cetirizine HCl Tablets, USP 10 mg
ANTIHISTAMINE

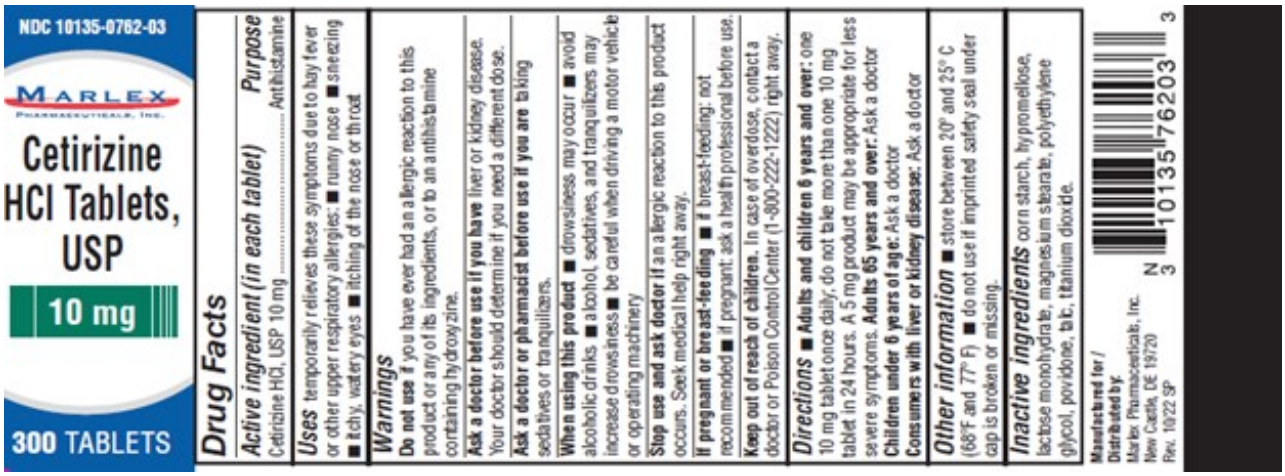
100 TABLETS

PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label

NDC 10135-0762-03

Allergy Relief
Cetirizine HCl Tablets, USP 10 mg
ANTIHISTAMINE

300 TABLETS

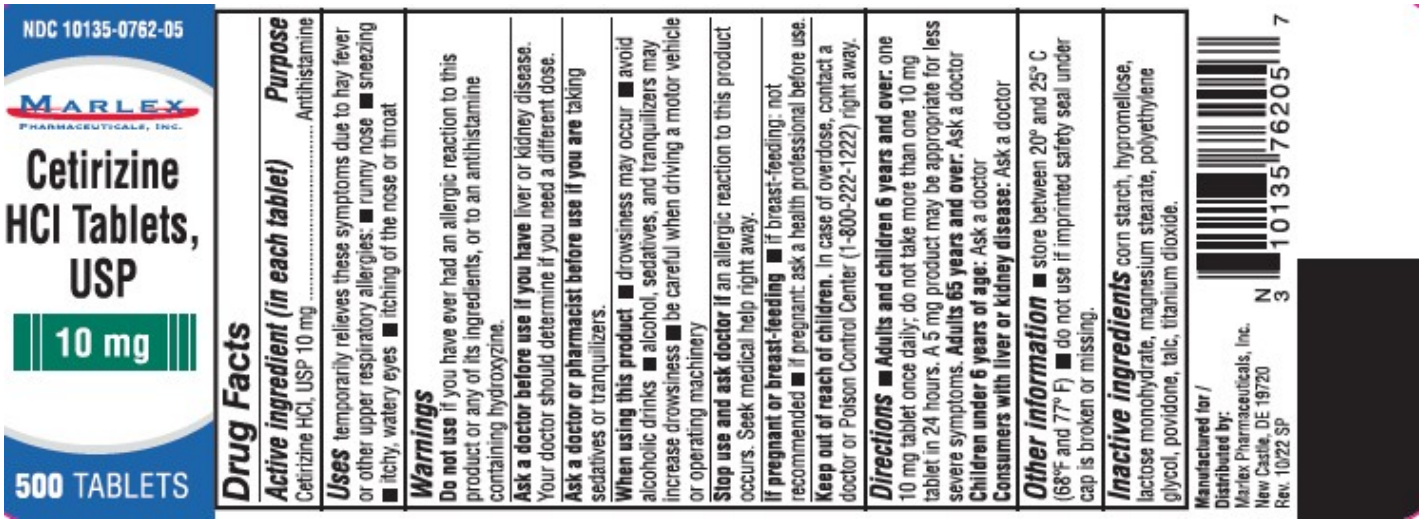


PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label

NDC 10135-0762-05

Allergy Relief
Cetirizine HCl Tablets, USP 10 mg
ANTIHISTAMINE

500 TABLETS



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10135-762
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
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	white	**Score**	no score
Shape	RECTANGLE (rounded-off)	**Size**	9mm
Flavor		**Imprint Code**	RI52
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10135-762-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	
2	NDC:10135-762-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	
3	NDC:10135-762-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	
4	NDC:10135-762-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	
5	NDC:10135-762-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077498	10/01/2022	

Labeler - Marlex Pharmaceuticals, Inc (782540215)

Revised: 10/2023 Marlex Pharmaceuticals, Inc