CETIRIZINE- cetirizine hydrochloride tablet, film coated
Major Pharmaceuticals
Reference Label Set Id: 06390749-5795-4e50-94bd-acb4b96e4b83

Major Pharmaceuticals Cetirizine 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 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 20-25˚C (68-77˚F)
- do not use if printed foil under cap is broken or missing

Inactive ingredients

corn starch, FD&C blue no. 1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin

Questions or comments?

1-800-616-2471

Principal Display Panel

MAJOR®

Compare to active ingredient in Zyrtec®

Original Prescription Strength

Cetirizine

Hydrochloride Tablets, 10 mg/Antihistamine

All Day Allergy Relief

INDOOR & OUTDOOR ALLERGIES

24 HOUR RELIEF OF:

Sneezing

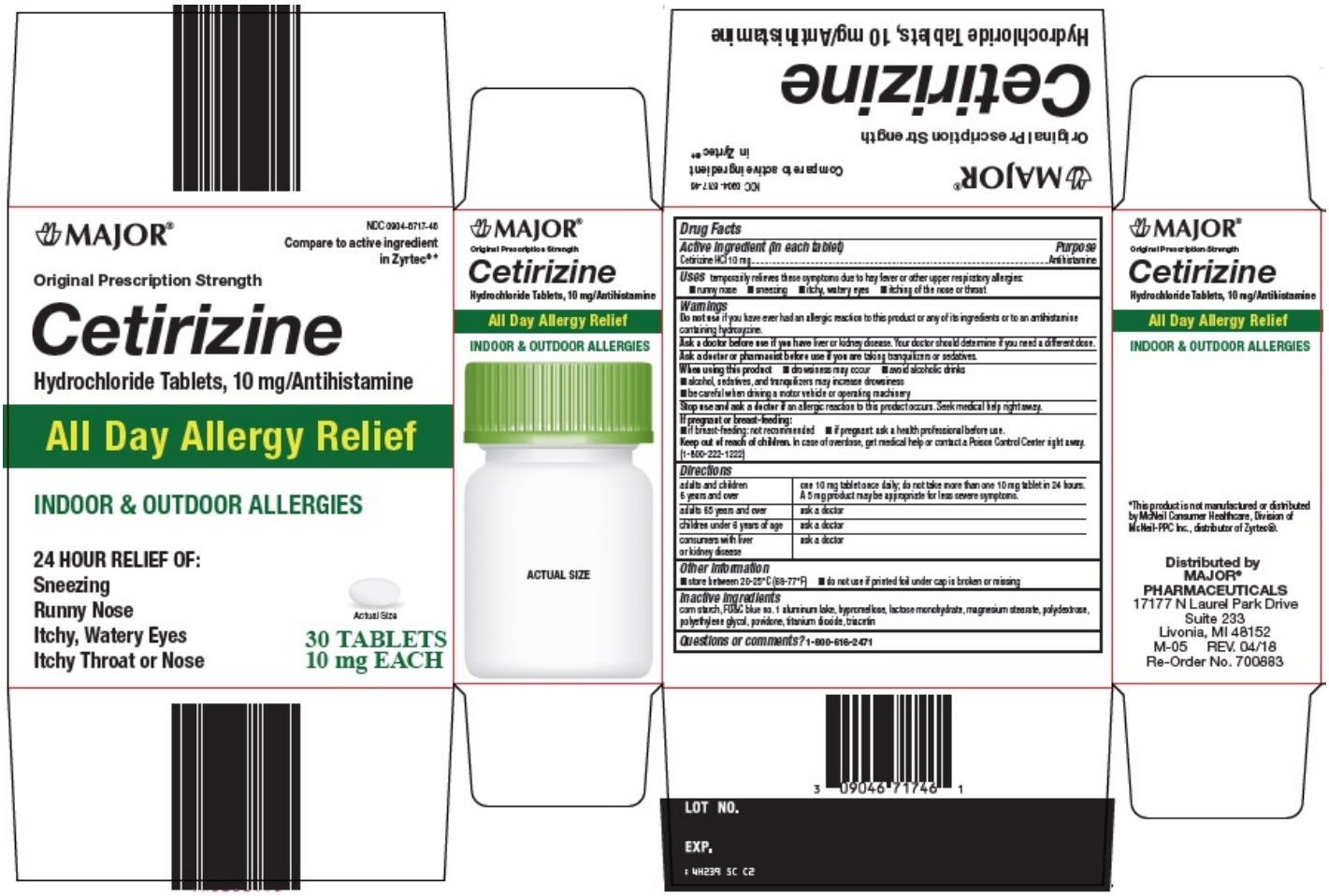
Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose

Actual Size

30 TABLETS 10 mg EACH



CETIRIZINE

cetirizine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-6717
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
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	4H2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6717-41	14 in 1 CARTON	06/29/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0904-6717-43	1 in 1 CARTON	07/03/2018	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0904-6717-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/03/2018	
4	NDC:0904-6717-72	1 in 1 CARTON	07/03/2018	
4		300 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0904-6717-60	1 in 1 CARTON	07/03/2018	
5		100 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0904-6717-86	1 in 1 CARTON	07/03/2018	
6		90 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0904-6717-46	1 in 1 CARTON	07/03/2018	

7		30 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:0904-6717-61	100 in 1 CARTON	06/29/2018	
8		1 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	ANDA078336	06/29/2018	

Labeler - Major Pharmaceuticals (191427277)

Revised: 4/2025 Major Pharmaceuticals