ALLERGY RELIEF- cetirizine hydrochloride tablet, film coated Spirit Pharmaceutical LLC

Allergy Relief

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	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)

Inactive ingredients

colloidal silicon dioxide*, croscarmellose sodium*, hypromellose, lactose, magnesium stearate, maize starch*, microcrystalline cellulose*, polyethylene glycol, povidone*, titanium dioxide

*containes one or more of these ingrdients

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in Zyrtec®*

All Day Allergy Relief

Cetirizine HCl 10mg

120 Tablets





CABINET:

All Day Allergy Relief Refill

COMPARE TO THE ACTIVE INGREDIENT IN: Zyrtec®*

Cetirizine HCI 10 mg

24-HOUR RELIEF OF:

RUNNY NOSE · ITCHY, WATERY EYES · SNEEZING ITCHY THROAT

120 TABLETS



TO OPEN:

- 1. POSITION THUMBS INSIDE THE SHORT FLANGE OVER THE LOCKS.
- 2. GRIP WHILE PIVOTING THUMBS OUTWARD TO OPEN THE LOCKS.

Tamper evident: do not use if pouch is open

Drug Facts

Active ingredient (in each tablet)

Purpose

Cetirizine HCl 10 mgAntihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • ltchy, watery eyes · sneezing · Itching of the nose or throat

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 pharmedist 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 & children 6 years & 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 & over	ask a doctor		
children under 6 years of age	ask a doctor		
consumers with liver or kidney dissesse	ask a doctor		

Drug Facts (continued)

Other Information - store between 20° to 25°C (68° to 77°F)

inactive ingredients Lactose, povidone, maize starch, magnesium stearate, purified water, titanium dioxide, hypromeliose, macrogol

Questions or comments? 1-888-333-9792

Say bye to allergies (and plastic waste).

- "This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Zyrtec®
- † Less than the limit of detection. and consistent with gluten-free diet labeling per FDA



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Lat / Expiration 🔝









ALLERGY RELIEF

cetirizine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4230
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZ INE HYDROCHLORIDE	10 mg	

Inactive Ingredients			
Ingredient Name	Strength		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
POVIDONE (UNII: FZ989GH94E)			
STARCH, CORN (UNII: O8232NY3SJ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			

Product Characteristics				
Color	white (white to off-white)	Score	2 pieces	
Shape	RECTANGLE (rounded-off rectangular biconvex tablet)	Size	10mm	
Flavor		Imprint Code	G4	
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:68210- 4230-1	120 in 1 POUCH; Type 0: Not a Combination Product	11/16/2022		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209274	11/16/2022	

Labeler - Spirit Pharmaceutical LLC (179621011)

Revised: 12/2023 Spirit Pharmaceutical LLC