CABINET 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

	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®*

Allergy Relief

Cetirizine HCl 10mg

100 Tablets

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Zyrtec®



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Drug Facts (continued)

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medical help or contact a Poison Control Center right
away. (1-803-222-1222)

Directions

adults and children 6 years and over	one 10 mg caplet once daily; do not take more than one 10 mg caplet in 24 hours. A5 mg product may be appropriate for less severe symptoms.
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consumers with liver or kidney disease	ask a doctor

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Questions or comments? 1-888-333-9792

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ALLERGY RELIEF

Cetirizine hydrochloride caplets, 10 mg / antihistamine

24 hour relief of:

- · runny nose
- sneezing
- · itchy, watery eyes
- · itching of the nose or throat

30 caplets

Actual Size

This product is not manufactured or distributed by McNeil Consumer Healthcare Division of McNeil L-PPC, Inc., owner of the registered trademark Zyriec*.

Distributed By: Spirit Pharmaceuticals, LLC Ronkonkoma, NY 11779 ORIG 09MB

Made in ladia

(VALUMEDS¥)

Compare to the active ingredient in Zyrtec^{®†} NOC 68210-0119-3

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KEEP CARTON FOR COMPLETE PRODUCT INFORMATION

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If program or broast-feeding:

mif breast-feeding; not recommended



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CABINET ALLERGY RELIEF

cetirizine hydrochloride tablet, film coated

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0119			
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				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)					
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)					
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)

Product Cl	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									

P	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:68210- 0119-0	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/25/2019					
2	NDC:68210- 0119-3	1 in 1 CARTON	03/10/2020					
2		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product						
3	NDC:68210- 0119-1	300 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2020					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA209274	10/25/2019				

Labeler - Spirit Pharmaceutical LLC (179621011)

Revised: 12/2023 Spirit Pharmaceutical LLC