ZYRTEC- cetirizine hydrochloride tablet, film coated Bryant Ranch Prepack

ZYRTEC®

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° to 25°C (68° to 77°F)
- do not use if imprinted foil inner seal on bottle is broken or missing

Inactive ingredients

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

Questions?

call 1-800-343-7805



CETIRIZINE HYDRO CHLO RIDE (UNII: 640047KTOA) (CETIRIZINE -

ZYRTEC cetirizine hydrochloride tablet, film coated Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:63629-2798(NDC:50580-726) Route of Administration ORAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

CETIRIZINE

UNII:YO7261ME24)	HYDROCHLORIDE	10 mg
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Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28 O L1HH48)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
LACTO SE MO NO HYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics			
Color	WHITE	Score	2 pieces
Shape	RECTANGLE (rounded-off rectangular biconvex tablet)	Size	9 mm
Flavor		Imprint Code	ZYRTEC;10;MG
Contains			

F	Packaging			
#	# Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:63629-2798-1	30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63629-2798-2	100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:63629-2798-3	15 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA0 19835	10/01/2008	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-2798), RELABEL(63629-2798)

Revised: 4/2015 Bryant Ranch Prepack