CETIRIZINE HYDROCHLORIDE - cetirizine hydrochloride capsule, liquid filled
Strides Pharma Inc

DRUG FACTS

Active ingredient (in each capsule)

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 capsule once daily; do not take more than one 10 mg capsule 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 at 20°-25°C (68°-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- protect from light
- **do not use if tamper-evident seal under cap imprinted with "Sealed for your Protection" is broken or missing.**

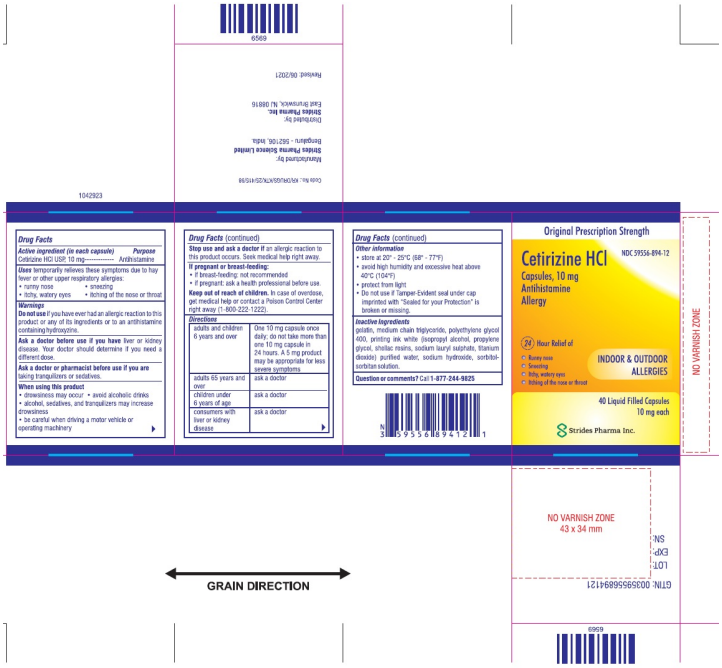
Inactive ingredients

gelatin, medium chain triglyceride, polyethylene glycol 400, printing ink white (isopropyl alcohol, propylene glycol, shellac resins, sodium lauryl sulphate, titanium dioxide) purified water, sodium hydroxide, sorbitol-sorbitan solution.

Questions or comments?

call 1-877-244-9825

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59556-894
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
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	YELLOW (colorless to pale yellow)	**Score**	no score
Shape	OVAL	**Size**	14mm
Flavor		**Imprint Code**	291
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-894-12	1 in 1 CARTON	07/21/2017	
1		40 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59556-894-77	1 in 1 CARTON	05/21/2018	
2		12 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:59556-894-79	7000 in 1 BAG; Type 0: Not a Combination Product	05/21/2018	
4	NDC:59556-894-78	1 in 1 CARTON	05/21/2018	
4		25 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205291	07/21/2017	

Labeler - Strides Pharma Inc (078868278)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	ANALYSIS(59556-894) , MANUFACTURE(59556-894) , PACK(59556-894)

Revised: 1/2023 Strides Pharma Inc