CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet Strive Pharmaceuticals Inc

Cetirizine HCl 10mg All-Day Allergy Relief

Cetirizine HCl 10 mg

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

- adults & 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: Ask a doctor
- consumers with liver or kidney disease: Ask a doctor

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 sedatives or tranquilizers.

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, ask a health professional before use.

Keep out of reach of children.

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OVERDOSE WARNING: In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Antihistamine

- store at room temperature between 20-25°C (68-77°F).
- close cap tightly after use.
- contains no ingredient made from a gluten-containing grain (wheat, barley or rye).

TAMPER EVIDENT: Do not use if imprinted safety seal is broken or missing.



Lot No. Exp. Date



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70692-139 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|---|-----------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| CETIRIZINE HYDRO CHLO RIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII: YO7261ME24) | CETIRIZINE HYDROCHLORIDE | 10 mg | |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | | |
| CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | |
| CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | | |

| Product Characteristics | | | |
|-------------------------|-----------|--------------|----------|
| Color | white | Score | 2 pieces |
| Shape | RECTANGLE | Size | 9 mm |
| Flavor | | Imprint Code | G;4 |
| Contains | | | |

| ı | Packaging | | | | |
|---|-----------|-----------------|---|-----------------------------|---------------------------|
| ı | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| l | 1 N | DC:70692-139-14 | 14 in 1 BOTTLE; Type 0: Not a Combination Product | 07/01/2020 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| ANDA | ANDA209274 | 07/01/2020 | |
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Labeler - Strive Pharmaceuticals Inc (080028013)

Revised: 11/2020 Strive Pharmaceuticals Inc