

DR SIMI CETIRIZINE HYDROCHLORIDE 10 MG- cetirizine hydrochloride 10 mg tablet, film coated
Farmacias De Similares TX LLC

Active Ingredient (in each tablet)

Cetirizine Hydrochloride 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

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

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 breastfeeding, not recommended
- if pregnant, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children

Overdosage

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

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)

Inactive ingredients

hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, polysorbate, povidone, pregelatinized starch, and titanium dioxide

Questions or comments?

855-280-1079

* This product is not manufactured or distributed by Kenvue Inc., the owner of the registered trademark Zyrtec®.

Distributed by:

FARMACIAS DE SIMILARES TX LLC

800 Brazos St Ste 260, Austin, TX, 78701, USA

customerservice@drsimi.com

www.drsimi.com

<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding: ■ if breast-feeding, not recommended ■ if pregnant, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p>Directions</p> <table border="1"> <tr> <td>Adults and children 6 years and over</td> <td>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</td> </tr> <tr> <td>Adults 65 years and over</td> <td>ask a doctor</td> </tr> <tr> <td>Children under 6 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>Consumers with liver or kidney disease</td> <td>ask a doctor</td> </tr> </table> <p>Other information</p> <p>■ Store between 20° to 25°C (68° to 77°F).</p> <p>Inactive ingredients hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, polysorbate, povidone, pregelatinized starch, and titanium dioxide</p>	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	<p>Drug Facts (continued)</p> <p>Questions or comments? 855-280-1079</p> <p>* This product is not manufactured or distributed by Kenvue Inc., the owner of the registered trademark Zyrtec®.</p> <p>Distributed by: FARMACIAS DE SIMILARES TX LLC 800 Brazos St Ste 260, Austin, TX, 78701, USA customerservice@drsimi.com www.drsimi.com</p>	<p>DR. SIMI </p> <p>NDC: 85786-203-30</p> <p>*Compares to Zyrtec® Allergy Original Prescription Strength</p> <p>Allergy Indoor & Outdoor Allergies</p> <p>Cetirizine Hydrochloride Tablets 10 mg</p> <p>Antihistamine</p> <p>24 hour relief of:</p> <ul style="list-style-type: none"> • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat or Nose <p>30 tablets 10 mg each</p>	<p>Drug Facts</p> <table border="1"> <tr> <td>Active ingredient (in each tablet)</td> <td>Purpose</td> </tr> <tr> <td>Cetirizine Hydrochloride 10 mg</td> <td>..... Antihistamine</td> </tr> </table> <p>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.</p> <p>Warnings</p> <p>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.</p> <p>Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.</p> <p>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</p> <p>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.</p> <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away. ▶</p>	Active ingredient (in each tablet)	Purpose	Cetirizine Hydrochloride 10 mg Antihistamine
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NDC: 85786-203-30

*Compares to Zyrtec® Allergy Original Prescription Strength

Allergy | Indoor & Outdoor Allergies

Cetirizine Hydrochloride
Tablets 10 mg

Antihistamine

24 hour relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

30 tablets

10 mg each

DR SIMI CETIRIZINE HYDROCHLORIDE 10 MG

cetirizine hydrochloride 10 mg tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85786-203
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
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	C;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85786-203-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076047	01/01/2026	

Labeler - Farmacias De Similares TX LLC (119489934)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp		057795122	pack(85786-203) , label(85786-203)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp		079157508	manufacture(85786-203)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp		968334974	manufacture(85786-203)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp		968335112	manufacture(85786-203)

Revised: 1/2026

Farmacias De Similares TX LLC