

**CETIRIZINE HCL- cetirizine tablet**  
**Strategic Sourcing Services LLC**

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**Drug Facts**

Cetirizine HCl 10 mg

Antihistamine

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

**Do not use** if you have ever had an allergic reaction to this product or any of its ingredients or 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 breastfeeding:**

- If breastfeeding: 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).

**Cetirizine Hydrochloride Tablets, USP 10 mg**

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°C to 25°C (68°F to 77°F)
- **do not use if imprinted foil inner seal on bottle is broken or missing.**
- FDA approved organic impurities test procedure differs from USP

colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, titanium dioxide.

### ***Questions or comments?***

Call **833-358-6431** Monday to Friday 9:00am to 7:00pm EST

Manufactured by:

#### **Glenmark Pharmaceuticals Limited**

Pithampur, Madhya Pradesh 454775, India

#### **Distributed by:**

#### **McKesson Corp. via SSSL**

Memphis, TN 38141

[www.fosterandthrive.com](http://www.fosterandthrive.com)

#### **Product of India**

February 2025

### **Package/Label Principal Display Panel**

#### Container label

NDC 70677-1279-5

10 mg - 300 Tablets

<p><b>VALUE PACK</b></p> <p>NDC 70677-1279-5</p> <p><b>Foster &amp; Thrive™</b></p> <p><b>ORIGINAL PRESCRIPTION STRENGTH</b></p> <p><b>All Day Allergy</b></p> <p><b>Cetirizine Hydrochloride Tablets USP, 10 mg</b></p> <p><b>ANTI-HISTAMINE</b></p> <p><b>Indoor &amp; Outdoor Allergies</b></p> <p><b>24 Hour Relief of:</b></p> <ul style="list-style-type: none"> <li>• Sneezing</li> <li>• Runny Nose</li> <li>• Itchy, Watery Eyes</li> <li>• Itchy Throat or Nose</li> </ul> <p><b>300 TABLETS</b> <b>10 MG EACH</b></p>		<p><b>Active ingredient (in each tablet).....Purpose</b> Cetirizine HCl 10 mg.....Antihistamine</p> <p><b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> <li>• runny nose</li> <li>• sneezing</li> <li>• itchy, watery eyes</li> <li>• itching of the nose or throat</li> </ul> <p><b>Warnings</b> <b>Do not use</b> if you ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.</p> <p><b>Ask a doctor before use if you have</b> liver or kidney disease. Your doctor should determine if you need a different dose. <b>Ask a doctor or pharmacist before use if you are</b> taking tranquilizers or sedatives.</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>• drowsiness may occur</li> <li>• avoid alcoholic drinks</li> <li>• alcohol, sedatives, and tranquilizers may increase drowsiness</li> <li>• be careful when driving a motor vehicle or operating machinery</li> </ul> <p><b>Stop use and ask a doctor</b> if an allergic reaction to this product occurs. Seek medical help right away.</p> <p><b>If pregnant or breastfeeding:</b></p> <ul style="list-style-type: none"> <li>• if breastfeeding: not recommended</li> <li>• if pregnant: ask a health professional before use.</li> </ul>	<p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p><b>Directions</b> <b>Adults and children 6 years and over:</b> 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. <b>Adults 65 years and over:</b> ask a doctor. <b>Children under 6 years of age:</b> ask a doctor. <b>Consumers with liver or kidney disease:</b> ask a doctor.</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• store between 20°C to 25°C (68°F to 77°F)</li> <li>• <b>do not use if imprinted foil inner seal on bottle is broken or missing.</b></li> <li>• FDA approved organic impurities test procedure differs from USP</li> </ul> <p><b>Inactive ingredients</b> colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, titanium dioxide.</p> <p><b>Questions or comments?</b> Call <b>833-358-6431</b> Monday to Friday 9:00am to 7:00pm EST.</p>
		<p>©2023 McKesson Corporation</p> <p><b>Distributed by:</b></p> <p>McKesson Corp., via SSSL Memphis, TN 38141 Money Back Guarantee www.fosterandthrive.com MP/DRUGS/25/9/2010 PE685500125-1 Rev. 1/25</p>	

## Package/Label Principal Display Panel

Carton label

NDC 70677-1279-5

10 mg- 300 Tablets

  
 NDC 70677-1279-5 COMPARE TO ZYRTEC® TABLETS ACTIVE INGREDIENT\*  
 Foster & Thrive™  
 ORIGINAL PRESCRIPTION STRENGTH  
**All Day Allergy**  
 Cetirizine Hydrochloride  
 Tablets USP, 10 mg  
 ANTIHISTAMINE  
 Indoor and Outdoor Allergies  
 300 TABLETS  
 10 MG EACH

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**VALUE PACK**

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**VALUE PACK**

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NDC 70677-1279-5 COMPARE TO ZYRTEC® TABLETS ACTIVE INGREDIENT\*  
 Foster & Thrive™  
 ORIGINAL PRESCRIPTION STRENGTH  
**All Day Allergy**  
 Cetirizine Hydrochloride  
 Tablets USP, 10 mg  
 ANTIHISTAMINE  
 Indoor & Outdoor Allergies  
 24 Hour Relief of:
 

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

 ACTUAL SIZE  
**300 TABLETS  
10 MG EACH**

**IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THIS CARTON FOR IMPORTANT INFORMATION.**

**Drug Facts**

**Active ingredient (in each tablet) Purpose**  
 Cetirizine HCl 10 mg.....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**  
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 ■ drowsiness may occur  
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 ■ alcohol, sedatives, and tranquilizers may increase drowsiness

**Drug Facts** (continued)

■ 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 breastfeeding:**  
 ■ if breastfeeding: not recommended  
 ■ if pregnant: ask a health professional before use.

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**Drug Facts** (continued)


**Other information**  
 ■ store between 20°C to 25°C (68°F to 77°F)  
 ■ do not use if imprinted foil inner seal on bottle is broken or missing  
 ■ FDA approved organic impurities test procedure differs from USP



**Inactive ingredients**  
 colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, titanium dioxide.

**Questions or comments?**  
 Call 833-358-6431 Monday to Friday 9:00am to 7:00pm EST

\*This product is not manufactured or distributed by Kenvue Brands LLC, distributor of Zyrtec® Tablets, and/or Kenvue Inc., or UCB Biopharma SRL, owner of the registered trademark Zyrtec®, respectively. (Neither Kenvue Brands/UCB Biopharma nor Kenvue make or license this product.)

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 Money Back Guarantee  
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 MP/BRUGS/25/9/2010  
 PE68551025-1  
 Rev. 1/23

  
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<b>CETIRIZINE HCL</b>			
cetirizine tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70677-1279
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			

Ingredient Name	Basis of Strength	Strength
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	C;17
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1279-2	1 in 1 CARTON	03/01/2025	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70677-1279-3	1 in 1 CARTON	03/01/2025	
2		60 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:70677-1279-4	1 in 1 CARTON	03/01/2025	
3		90 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:70677-1279-5	1 in 1 CARTON	03/01/2025	
4		300 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	ANDA078427	03/01/2025	

**Labeler** - Strategic Sourcing Services LLC (116956644)

**Establishment**

Name	Address	ID/FEI	Business Operations
Glenmark Pharmaceuticals Limited		862603186	ANALYSIS(70677-1279, 70677-1279, 70677-1279, 70677-1279) , MANUFACTURE(70677-1279, 70677-1279, 70677-1279, 70677-1279)

Revised: 2/2025

Strategic Sourcing Services LLC