

# Cetirizine Hydrochloride Tablets, 5 mg

## Revised Final Printed - 100 Tablets Container Label

Do not use if imprinted foil inner seal on bottle is broken or missing.

NDC-64679-988-01

**Cetirizine HCl**  
Tablets

**ALLERGY**

**5 mg**

**Antihistamine**

100 Tablets

**WOCKHARDT**

**Active ingredient (in each tablets)**  
Cetirizine HCl 10 mg.....Antihistamine

**Purpose**  
Use 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 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.

**Directions Adults and children 6 years and over:** 1 or 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours. **Adults 65 years and over:** 1 tablet once a day; do not take more than 1 tablet in 24 hours. **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°). **Inactive ingredients** colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, Titanium dioxide.


**Questions ? Call 1-866-822-8965**

**Manufactured by:** Wockhardt Limited, Mumbai, India.

**Distributed by:** Wockhardt USA Inc., 135 Route 202/206, Bedminster, NJ 07921 USA.

Lot: Non Varnish Area

Exp: Non Varnish Area



6467998801

Actual size : 30 mm x 120 mm

<b>Labeling Format Information:</b>		
<b>Fonts:</b> Helvetica Narrow medium, bold, bold oblique		
<b>Drug Facts</b>	NA	<b>Leading</b> 5 pt
<b>Headings</b>	4.8 pt	<b>Solid Circle Bullets</b> 4.8 pt
<b>Subheader</b>	4.8 pt	<b>Barline</b> NA
<b>Body Text</b>	4.8 pt	<b>Hairline</b> NA
<b>Drug Facts (continued):</b> NA		

# Cetirizine Hydrochloride Tablets, 5 mg

## Revised Final Printed - 100 Tablets Bottle Carton

### Drug Facts

<b>Active ingredient (in each tablet)</b>	<b>Purpose</b>
Cetirizine HCl 5 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**  
**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. ▼

### Drug Facts (continued)

**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.

<b>Directions</b>	
adults and children 6 years and over	1 or 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.
adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in 24 hours.
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor ▼

### Drug Facts (continued)

**Other information** • store between 20° to 25°C (68° to 77°F)

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

 **Questions ?** call 1-866-822-8965

Do not use if imprinted foil inner seal on bottle is broken or missing

MH/DRUGS/AD/068

**Manufactured by:**  
Wockhardt Limited,  
Mumbai, India.

**Distributed by:**  
Wockhardt USA Inc.,  
135 Route 202/206,  
Bedminster, NJ 07921  
USA.

Iss 201207

<b>Labeling Format Information:</b>	
Font: Helvetica Narrow medium, bold, bold oblique	
Drug Facts	9 pt
Headings	8 pt
Subheader	6.5 pt
Body Text	6.5 pt
Drug Facts (continued)	8 pt
	Lending
	Solid Circle Bullets
	Barline
	Hairline
	6.5 pt
	6.5 pt
	1 pt
	.5 pt

Exp.:

Lot:



NDC 64679-988-01

Original Prescription Strength

# Cetirizine HCl Tablets



## 5 mg

### Antihistamine

Indoor & Outdoor  
Allergies

24 hour

Relief of

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

100 Tablets



Size:  
95 x 45 x 75 mm

# Cetirizine Hydrochloride Tablets, 10 mg

## Revised Final Printed - 100 Tablets Container Label

Do not use if imprinted foil inner seal on bottle is broken or missing.

NDC-64679-989-01

**Cetirizine Hcl Tablets**

**10 mg**

**Antihistamine**

100 Tablets

**WOCKHARDT**

**Active ingredient (in each tablets)**  
Cetirizine HCl 10 mg.....Antihistamine

**Purpose**  
Use 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 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. **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°). **Inactive ingredients** colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, titanium dioxide. **Questions ? Call 1-866-822-8965**

**Manufactured by:** Wockhardt Limited, Mumbai, India. **Distributed by:** Wockhardt USA Inc., 135 Route 202/206, Bedminster, NJ 07921 USA.

Lot: **Non Varnish Area**

Actual size : 30 mm x 120 mm

Labeling Format Information:			
Fonts: Helvetica Narrow medium, bold, bold oblique			
Drug Facts	NA	Leading	5 pt
Headings	4.8 pt	Solid Circle Bullets	4.8 pt
Subheader	4.8 pt	Barline	NA
Body Text	4.8 pt	Hairline	NA
Drug Facts (continued): NA			

# Cetirizine Hydrochloride Tablets, 10 mg

## Revised Final Printed - 100 Tablets Bottle Carton

### 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

**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.

### Drug Facts (continued)

**Ask a doctor or pharmacist before use if you are** taking tranquilizers or sedatives.

### When using this product

- drowsiness may occur • avoid alcohol 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.

### 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

### Drug Facts (continued)

**Other information** • store between 20° to 25°C (68° to 77°F)

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



**Questions ?** call 1-866-822-8965

Do not use if imprinted foil inner seal on bottle is broken or missing

MH/DRUGS/AD/068

**Manufactured by:**  
Wockhardt Limited,  
Mumbai, India.

**Distributed by:**  
Wockhardt USA Inc.,  
135 Route 202/206,  
Bedminster, NJ 07921  
USA.

Iss 201207

<b>Labeling Format Information:</b>	
Font: Helvetica Narrow medium, bold, bold oblique	
Drug Facts	9 pt
Headings	8 pt
Subheader	6.5 pt
Body Text	6.5 pt
Drug Facts (continued):	8 pt
	Leading
	Solid Circle Bullets
	Barline
	Hairline
	6.5 pt
	6.5 pt
	1 pt
	.5 pt

Exp.:

Lot:



NDC 64679-989-01

Original Prescription Strength

**Cetirizine HCl Tablets**

ALLERGY

**10 mg**

**Antihistamine**

Indoor & Outdoor  
Allergies

**24 hour  
Relief of**

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

**100 Tablets**



Size:  
95 x 45 x 75 mm

# Cetirizine Hydrochloride Tablets, 5 mg

## Wockhardt's Proposed 14 Tablets Blister Card



Actual size : 75 mm x 145 mm

# Cetirizine Hydrochloride Tablets, 5 mg

Revised Final Printed - 14 Unit Dose (1 x 14's) Blister Carton

**5 mg**  
*Cetirizine HCl Tablets*

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**24 hour**  
Relief of  
• Sneezing  
• Runny Nose  
• Itchy, Watery Eyes  
• Itchy Throat or Nose

**Antihistamine**

**5 mg**

**Cetirizine HCl Tablets**

*Original Prescription Strength*  
NDC 64679-988-07

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**Cetirizine HCl Tablets**  
**5 mg**

**Cetirizine HCl Tablets**  
**5 mg**

**14 Unit Dose Tablets**  
(1 x 14 Tablets)  
**Indoor & Outdoor**  
**Allergies**

**5 mg**  
*WOCKHARDT*

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b> Cetirizine HCl 5 mg</p> <p><b>Purpose</b> Antihistamine</p> <p><b>Uses</b> 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><b>Warnings</b> 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. <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. <b>When using this product</b> • drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery <b>Stop use and ask a doctor if</b> an allergic reaction to this product occurs. Seek medical help right away. <b>If pregnant or breast-feeding:</b> • if breast-feeding: not recommended • if pregnant: ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">adults and children 6 years and over</td> <td>1 or 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.</td> </tr> <tr> <td>adults 65 years and over</td> <td>1 tablet once a day; do not take more than 1 tablet in 24 hours.</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>	adults and children 6 years and over	1 or 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.	adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in 24 hours.	children under 6 years of age	ask a doctor	consumers with liver or kidney disease	ask a doctor	<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b> • store between 20° to 25°C (68° to 77°F)</p> <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 ?</b> call 1-866-822-8965</p> <p style="text-align: center;"><b>Do not use if the individual blister unit is open or torn</b></p> <div style="text-align: center;">  <p>3 64679 98807 7</p> </div> <p><b>Manufactured by:</b> Wockhardt Limited, Mumbai, India.</p> <p><b>Distributed by:</b> Wockhardt USA Inc., 135 Route 202/206, Bedminster, NJ 07921 USA.</p> <p style="text-align: right;">Iss.201207</p>
adults and children 6 years and over	1 or 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.								
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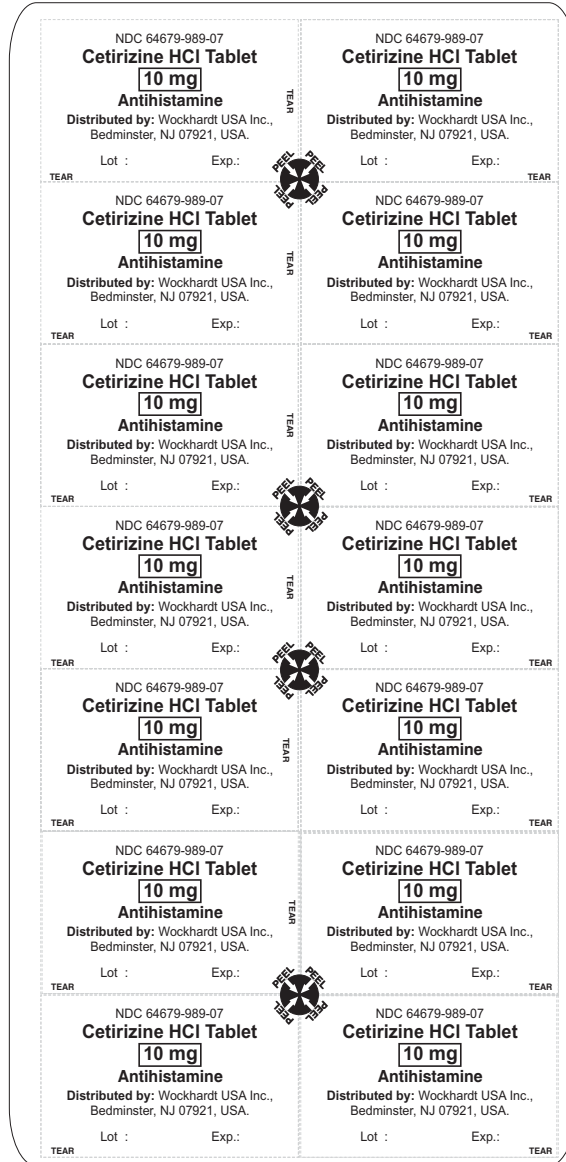
LOT :  
Exp. :

Actual Size: 196 x 16 x 90 mm

<b>Labeling Format Information:</b>	
Fonts: Helvetica Narrow medium, bold, bold oblique	
<b>Drug Facts</b>	9 pt
<b>Headings</b>	8 pt
<b>Subheader</b>	6.5 pt
<b>Body Text</b>	6.5 pt
<b>Drug Facts (continued):</b>	8 pt
<b>Leading</b>	6.5 pt
<b>Solid Circle Bullets</b>	6.5 pt
<b>Barline</b>	1.5 pt
<b>Hairline</b>	.5 pt

# Cetirizine Hydrochloride Tablets, 10 mg

## Wockhardt's Proposed 14 Tablets Blister Card



Actual size : 75 mm x 145 mm

# Cetirizine Hydrochloride Tablets, 10 mg

Revised Final Printed - 14 Unit Dose (1 x 14's) Blister Carton

**Cetirizine HCl Tablets**  
10 mg

**Antihistamine**

**10 mg**

**Cetirizine HCl Tablets**

*Original Prescription Strength*

NDC 64679-989-07

**Cetirizine HCl Tablets**  
10 mg

14 Unit Dose Tablets  
(1 x 14 Tablets)

Indoor & Outdoor  
Allergies

**24 hour**  
Relief of

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

*WOCKHARDT*

Cetirizine HCl Tablets  
10 mg

**Cetirizine HCl Tablets**  
10 mg

<p><b>Drug Facts</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 50%;">Active ingredient (in each tablet)</th> <th style="width: 50%;">Purpose</th> </tr> <tr> <td>Cetirizine HCl 10 mg</td> <td>Antihistamine</td> </tr> </table> <p><b>Uses</b> 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><b>Warnings</b> 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. <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 if</b> an allergic reaction to this product occurs. Seek medical help right away. <b>If pregnant or breast-feeding:</b></p> <ul style="list-style-type: none"> <li>• If breast-feeding: 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.</p> <p><b>Directions</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">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>	Active ingredient (in each tablet)	Purpose	Cetirizine HCl 10 mg	Antihistamine	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><b>Drug Facts</b> (continued)</p> <p><b>Other information</b> • store between 20° to 25°C (68° to 77°F)</p> <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 ?</b> call 1-866-822-8965</p> <p style="text-align: center;"><b>Do not use if the individual blister unit is open or torn</b></p> <div style="text-align: center;"> <p>6 4 6 7 9 9 8 9 0 7 1 4</p> </div> <p><b>Manufactured by:</b> Wockhardt Limited, Mumbai, India.</p> <p><b>Distributed by:</b> Wockhardt USA Inc., 135 Route 202/206, Bedminster, NJ 07921 USA.</p> <p style="text-align: right;">Iss 201207</p>
Active ingredient (in each tablet)	Purpose												
Cetirizine HCl 10 mg	Antihistamine												
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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												

LOT: \_\_\_\_\_  
Exp.: \_\_\_\_\_

Actual Size: 196 x 90 x 16 mm

<b>Labeling Format Information:</b>	
Fonts: Helvetica Narrow medium, bold, bold oblique	
Drug Facts	9 pt
Headings	8 pt
Subheader	6.5 pt
Body Text	6.5 pt
Drug Facts (continued):	8 pt
Leading	6.5 pt
Solid Circle Bullets	6.5 pt
Barline	1.5 pt
Hairline	.5 pt





# Cetirizine Hydrochloride Tablets, 5 mg

Revised Final Printed - 30 (1 x 30's) Tablet Blister Carton

**5 mg**  
*Cetirizine HCl Tablets*

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**30 Unit Dose Tablets**  
(1 x 30 Tablets)  
**Allergies**  
Indoor & Outdoor

**Antihistamine**

**24 hour**  
Relief of  
• Sneezing  
• Runny Nose  
• Itchy, Watery Eyes  
• Itchy Throat or Nose

**5 mg**

**Cetirizine HCl Tablets**

*Original Prescription Strength*  
NDC 64679-988-04

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**Cetirizine HCl Tablets**  
**5 mg**

**Cetirizine HCl Tablets**  
**5 mg**

LOT:  
Exp.:

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b> <span style="float: right;"><b>Purpose</b></span> Cetirizine HCl 5 mg .....Antihistamine</p> <p><b>Uses</b> 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><b>Warnings</b> 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. <b>When using this product</b> • drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery <b>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</b> <b>If pregnant or breast-feeding:</b> • If breast-feeding: not recommended • If pregnant: ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">adults and children 6 years and over</td> <td>1 or 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.</td> </tr> <tr> <td>adults 65 years and over</td> <td>1 tablet once a day; do not take more than 1 tablet in 24 hours.</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>	adults and children 6 years and over	1 or 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.	adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in 24 hours.	children under 6 years of age	ask a doctor	consumers with liver or kidney disease	ask a doctor	<p><b>Drug Facts (continued)</b></p> <p><b>Other information</b> • store between 20° to 25°C (68° to 77°F)</p> <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 ?</b> call 1-866-822-8965</p> <p style="text-align: center;"><b>Do not use if the individual blister unit is open or torn</b></p> <div style="text-align: center;"> <p style="font-size: small;">3 64679 98804 6</p> </div> <p><b>Manufactured by:</b> Wockhardt Limited, Mumbai, India.</p> <p><b>Distributed by:</b> Wockhardt USA Inc., 135 Route 202/206, Bedminster, NJ 07921 USA.</p> <p style="text-align: right;">Iss 201207</p>
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adults 65 years and over	1 tablet once a day; do not take more than 1 tablet in 24 hours.								
children under 6 years of age	ask a doctor								
consumers with liver or kidney disease	ask a doctor								

Actual Size: 185 x 94 x 15 mm

<b>Labeling Format Information:</b>			
Fonts: Helvetica Narrow medium, bold, bold oblique			
Drug Facts	9 pt	Leading	6.5 pt
Headings	8 pt	Solid Circle Bullets	6.5 pt
Subheader	6.5 pt	Barline	1.5 pt
Body Text	6.5 pt	Hairline	.5 pt
Drug Facts (continued):	8 pt		



# Cetirizine Hydrochloride Tablets, 10 mg

Revised Final Printed - 30 (1 x 30's) Tablet Blister Carton

**10 mg**  
*Cetirizine HCl Tablets*

**24 hour Relief of**

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



**30 Unit Dose Tablets**  
(1 x 30 Tablets)

**10 mg**

**Cetirizine HCl Tablets**

*Original Prescription Strength*

NDC 64679-989-04



**Indoor & Outdoor Allergies**

**10 mg**  
*Cetirizine HCl Tablets*

**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**  
**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.

**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

**Drug Facts (continued)**

**Other information** • store between 20° to 25°C (68° to 77°F)

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

 **Questions ?** call 1-866-822-8965

**Do not use if the individual blister unit is open or torn**



3 64679 989804 6

**Manufactured by:**  
Wockhardt Limited,  
Mumbai, India.

**Distributed by:**  
Wockhardt USA Inc.,  
135 Route 202/206,  
Bedminster, NJ 07921  
USA.

Iss 201207

LOT :  
Exp. :

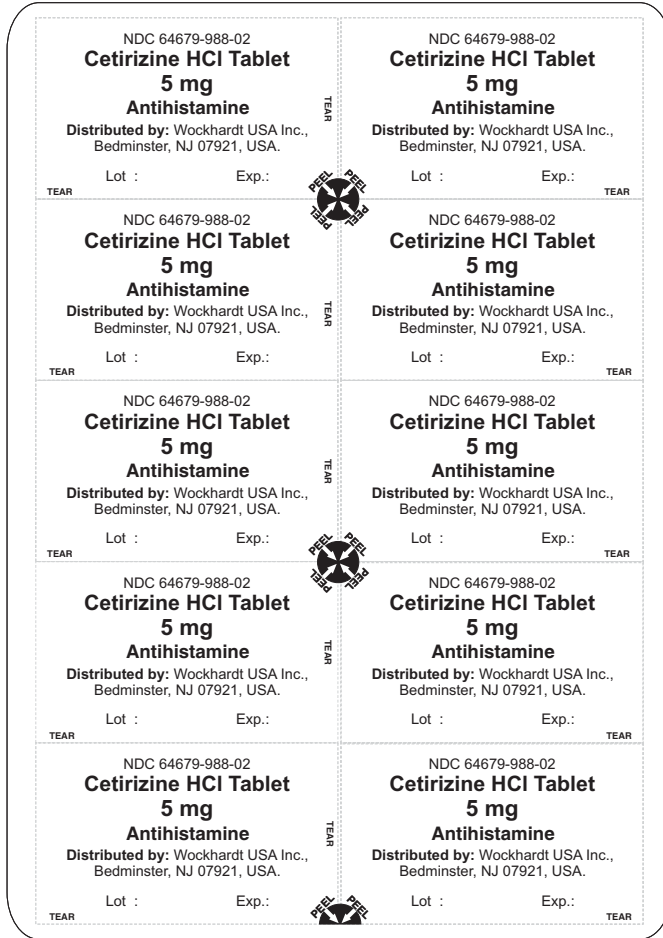
Cetirizine HCl Tablets  
10 mg

Actual Size: 185 x 94 x 15 mm

<b>Labeling Format Information:</b>			
Fonts: Helvetica Narrow medium, bold, bold oblique			
<b>Drug Facts</b>	9 pt	<b>Leading</b>	6.5 pt
<b>Headings</b>	8 pt	<b>Solid Circle Bullets</b>	6.5 pt
<b>Subheader</b>	6.5 pt	<b>Barline</b>	1.5 pt
<b>Body Text</b>	6.5 pt	<b>Hairline</b>	.5 pt
<b>Drug Facts (continued):</b>	8 pt		

# Cetirizine Hydrochloride Tablets, 5 mg

## Wockhardt's Proposed 10 Tablets Blister Card



Actual size : 88 mm x 124 mm

# Cetirizine Hydrochloride Tablets, 5 mg

## Revised Final Printed - 100 Tablets Blister Carton

Do not use if the individual blister unit is open or torn

---

**Questions ?** call 1-866-822-8965

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

---

Other information • store between 20° to 25°C (68° to 77°F)

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Drug Facts (continued)

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1 or 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours.	adults and children 6 years and over
1 tablet once a day; do not take more than 1 tablet in 24 hours.	adults 65 years and over
ask a doctor	children under 6 years of age
ask a doctor	consumers with liver or kidney disease

**Directions**

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding:  
 • If pregnant: ask a health professional before use.  
 • If breast-feeding: not recommended.

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

When using this product:  
 • avoid alcoholic drinks  
 • drowsiness may occur  
 • alcohol, sedatives, and tranquilizers may increase drowsiness  
 • be careful when driving a motor vehicle or operating machinery

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

Ask a doctor before use if you have liver or kidney disease.  
 Your doctor should determine if you need a different dose.

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.

**Warnings**

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

**Uses**  
 Cetirizine HCl 5 mg  
 Antihistamine

**Drug Facts**

**Active ingredient (in each tablet)**  
 Antihistamine

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**Distributed by:**  
 Wockhardt USA Inc.,  
 135 Route 202/206,  
 Bedminster, NJ 07921  
 USA.

**Manufactured by:**  
 Wockhardt Limited,  
 Mumbai, India.

Iss 201207

MH/DRUGS/AD/068

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NDC 64679-988-02

Original Prescription Strength

# Cetirizine HCl Tablets

ALLERGY

## 5 mg

Antihistamine

Indoor & Outdoor Allergies

100 Unit Dose Tablets  
(10 x 10 Tablets)

24 hour Relief of

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

Lot: \_\_\_\_\_

Exp.: \_\_\_\_\_

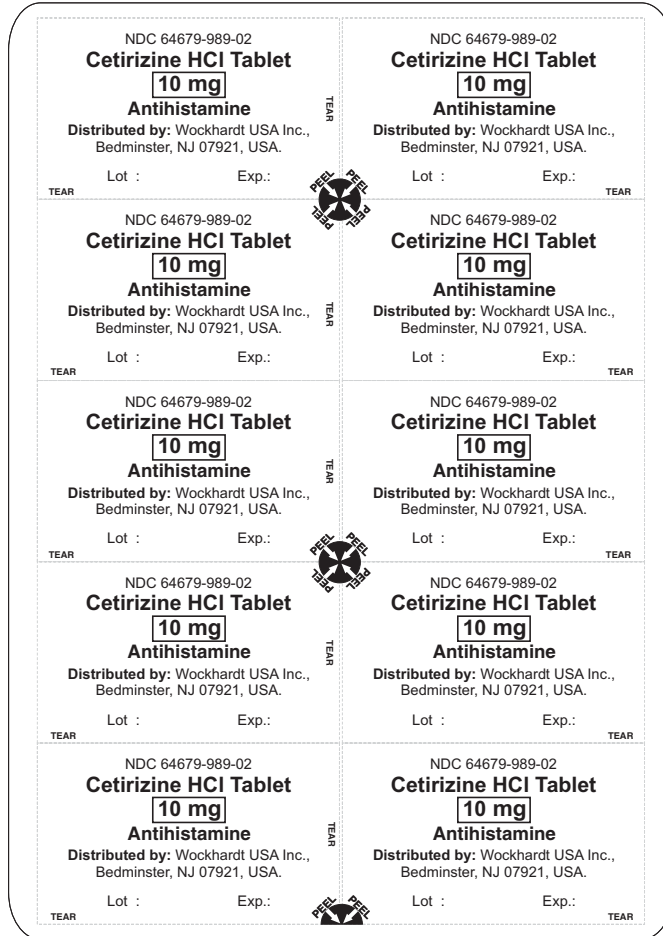
7 64679 98802 12

Actual Size: 135 x 45 x 95 mm

Labeling Format Information:			
Fonts: Helvetica Narrow medium, bold, bold oblique			
Drug Facts	9 pt	Leading	6.5 pt
Headings	8 pt	Solid Circle Bullets	6.5 pt
Subheader	6.5 pt	Barline	1 pt
Body Text	6.5 pt	Hairline	.5 pt
Drug Facts (continued):	8 pt		

# Cetirizine Hydrochloride Tablets, 10 mg

## Wockhardt's Proposed 10 Tablets Blister Card



Actual size : 88 mm x 124 mm

# Cetirizine Hydrochloride Tablets, 10 mg

## Revised Final Printed 100 - Tablets Blister Carton

Do not use if the individual blister unit is open or torn

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Questions ? call 1-866-822-8965

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

---

**Other Information** • store between 20° to 25° C (68° to 77° F)

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**Drug Facts** (continued)

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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.	ask a doctor
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

---

**Directions**  
 right away:  
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center.  
 • If pregnant: ask a health professional before use.  
 • If breast-feeding: not recommended.  
 • If pregnant or breast-feeding:  
 Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.  
 When using this product:  
 • alcohol, sedatives, and tranquilizers may increase drowsiness.  
 • avoid alcoholic drinks.  
 • drowsiness may occur.  
 • be careful when driving a motor vehicle or operating machinery.  
 Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.  
 Your doctor should determine if you need a different dose.  
 Ask a doctor before use if you have liver or kidney disease.  
 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.

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**Warnings**  
 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

---

**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

---

**Active Ingredient (in each tablet)**  
 Cetirizine HCl 10 mg  
**Purpose**  
 Antihistamine

---

**Distributed by:**  
 Wockhardt USA Inc.,  
 135 Route 202/206,  
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 USA.

**Manufactured by:**  
 Wockhardt Limited,  
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MHDRUGS/AD/068

Iss 201207

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NDC 64679-989-02

Original Prescription Strength

# Cetirizine HCl Tablets

ALLERGY

---

## 10 mg

### Antihistamine

Indoor & Outdoor Allergies

100 Unit Dose Tablets  
(10 x 10 Tablets)

24 hour Relief of

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

Lot: \_\_\_\_\_

Exp.: \_\_\_\_\_

6467998902

Actual Size: 135 x 45 x 95 mm

Labeling Format Information:			
Fonts: Helvetica Narrow medium, bold, bold oblique			
Drug Facts	9 pt	Leading	6.5 pt
Headings	8 pt	Solid Circle Bullets	6.5 pt
Subheader	6.5 pt	Barline	1 pt
Body Text	6.5 pt	Hairline	.5 pt
Drug Facts (continued):	8 pt		