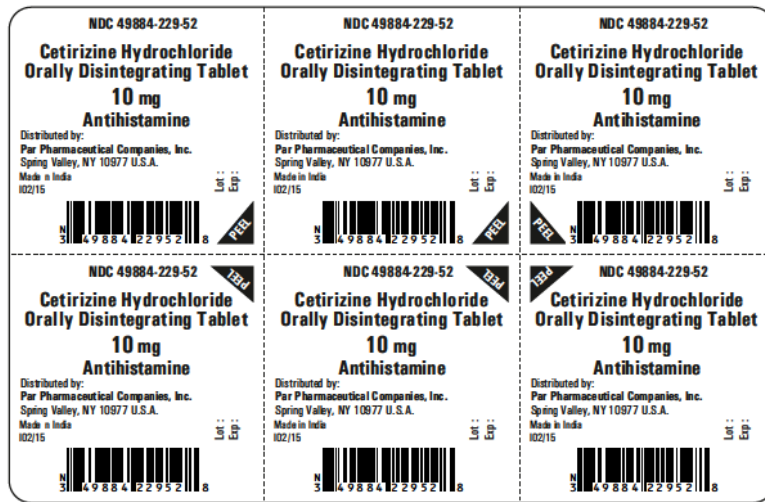


Proposed Blister Label for Cetirizine Hydrochloride Orally Disintegrating Tablets, 10 mg (6 tablets)



Proposed Carton Label for Cetirizine Hydrochloride Orally Disintegrating Tablets, 10 mg - 12 tablets (2X6)

Cetirizine Hydrochloride
Orally Disintegrating Tablets
10 mg
Antihistamine
Dissolve Tabs

NDC 49884 229 87

Cetirizine Hydrochloride
Orally Disintegrating Tablets
10 mg
Antihistamine

Dissolve Tabs

24 HOUR RELIEF OF

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

ALLERGY

INDOOR + OUTDOOR
ALLERGIES

12
ORALLY
DISINTEGRATING
TABLETS
10 mg each

Distributed by:
Par Pharmaceutical Companies, Inc.
Spring Valley, NY 10977 U.S.A.

Manufactured by:
Par Formulations Private Limited,
1/58, Pudupakkam,
Kelambakkam 603 103.
Made in India
10/2/15

Cetirizine Hydrochloride
Orally Disintegrating Tablets

Dissolve Tabs

Antihistamine
10 mg

Drug Facts		Drug Facts (continued)							
<p>Active ingredient (in each tablet) Purpose</p> <p>Cetirizine Hydrochloride 10 mg.....Antihistamine</p> <p>Uses</p> <p>temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> <li style="width: 50%;">• runny nose <li style="width: 50%;">• sneezing <li style="width: 50%;">• itchy, watery eyes <li style="width: 50%;">• itching of the nose or throat <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</p> <ul style="list-style-type: none"> <li style="width: 50%;">• drowsiness may occur <li style="width: 50%;">• avoid alcoholic drinks <li style="width: 50%;">• alcohol, sedatives, and tranquilizers may increase drowsiness <li style="width: 50%;">• be careful when driving a motor vehicle or operating machinery <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>If pregnant or breast-feeding:</p> <ul style="list-style-type: none"> • if breast-feeding: not recommended • if pregnant: ask a health professional before use. 	<p>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)</p> <p>Directions</p> <p>Tablet melts in mouth. Can be taken with or without water.</p> <table 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> <p>Other information</p> <ul style="list-style-type: none"> • store between 20° to 25°C (68° to 77°F). Avoid high humidity. • do not use if carton or blister unit is opened or broken • see side panel for lot number and expiration date <p>Inactive ingredients</p> <p>butyl hydroxyanisole, butyl hydroxytoluene, colloidal silicon dioxide, corn starch, croscopovidone, edetate disodium, hydroxy propyl beta cyclodextrin, magnesium stearate, microcrystalline cellulose, maize maltodextrin, peppermint and orange flavor, and sucralose.</p> <p>Questions? call 1-800-828-9393</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
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Cetirizine Hydrochloride
Orally Disintegrating Tablets

Antihistamine
10 mg

Dissolve Tabs

Cetirizine Hydrochloride
Orally Disintegrating Tablets

Antihistamine
10 mg

Un varnish Area

LOT: _____

EXP: _____

Proposed Carton Label for Cetirizine Hydrochloride Orally Disintegrating Tablets, 10 mg - 24 tablets (4X6)

Cetirizine Hydrochloride
Orally Disintegrating Tablets
10 mg
Antihistamine
Dissolve Tabs



190

NDC 49884 229 35

Original Prescription Strength

Cetirizine Hydrochloride
Orally Disintegrating Tablets
10 mg
Antihistamine

Dissolve Tabs



ALLERGY

INDOOR + OUTDOOR
ALLERGIES

24
ORALLY
DISINTEGRATING
TABLETS
10 mg each

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10/2/15



N
2 4 9 8 8 4 2 2 9 3 5 1

Cetirizine Hydrochloride
Orally Disintegrating Tablets
Dissolve Tabs
Antihistamine
10 mg

Cetirizine Hydrochloride
Orally Disintegrating Tablets
10 mg
Antihistamine
Un varnish Area

LOT: _____

EXP: _____

Drug Facts	Drug Facts (continued)								
<p>Active ingredient (in each tablet) Purpose Cetirizine Hydrochloride 10 mg.....Antihistamine</p> <p>Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> • runny nose • sneezing • itchy, watery eyes • itching of the nose or throat <p>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.</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</p> <ul style="list-style-type: none"> • drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>If pregnant or breast-feeding:</p> <ul style="list-style-type: none"> • if breast-feeding: not recommended • if pregnant: ask a health professional before use. 	<p>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)</p> <p>Directions Tablet melts in mouth. Can be taken with or without water.</p> <table 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> <p>Other information</p> <ul style="list-style-type: none"> • store between 20° to 25°C (68° to 77°F). Avoid high humidity. • do not use if carton or blister unit is opened or broken • see side panel for lot number and expiration date <p>Inactive ingredients butyl hydroxyanisole, butyl hydroxytoluene, colloidal silicon dioxide, corn starch, crospovidone, edetate disodium, hydroxy propyl beta cyclodextrin, magnesium stearate, microcrystalline cellulose, maize maltodextrin, peppermint and orange flavor, and sucralose.</p> <p>Questions? call 1-800-828-9393</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
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