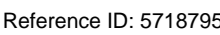




(b) (4)










# ZYRTEC Allergy oral solution 1mg/ml

NDA 22155/S029

## Draft Drug Facts Label

<h3>Drug Facts</h3>		<h3>Drug Facts (continued)</h3>											
<p><b>Active Ingredient</b>                      <b>Purpose</b>  <b>(In each 5 mL)</b>  Cetirizine HCl 5 mg.....Antihistamine</p>		<p><b>Directions</b>  ■ use only with enclosed dosing cup  ■ find right dose on chart below  ■ mL = milliliter</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>		<table border="1"> <tr> <td>adults and children 6 years and over</td> <td>5 mL or 10 mL once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours.</td> </tr> <tr> <td>adults 65 years and over</td> <td>5 mL once daily; do not take more than 5 mL in 24 hours.</td> </tr> <tr> <td>children 2 to under 6 years of age</td> <td>2.5 mL once daily. If needed, dose can be increased to a maximum of 5 mL once daily or 2.5 mL every 12 hours. Do not give more than 5 mL in 24 hours.</td> </tr> <tr> <td>children under 2 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	5 mL or 10 mL once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours.	adults 65 years and over	5 mL once daily; do not take more than 5 mL in 24 hours.	children 2 to under 6 years of age	2.5 mL once daily. If needed, dose can be increased to a maximum of 5 mL once daily or 2.5 mL every 12 hours. Do not give more than 5 mL in 24 hours.	children under 2 years of age	ask a doctor	consumers with liver or kidney disease	ask a doctor
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children under 2 years of age	ask a doctor												
consumers with liver or kidney disease	ask a doctor												
<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.</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><b>Other Information</b>  ■ each 5 mL contains: sodium 3.5 mg  ■ store between 20° to 25°C (68° to 77°F)  ■ do not use if carton is opened. Do not use if bottle wrap imprinted with "Sealed For Your Safety" is broken or missing  ■ see bottom panel for lot number and expiration date</p>											
<p><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  ■ in rare cases, you may experience itching after stopping cetirizine. Consult your healthcare provider if this happens.</p> <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:  ■ 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 right away. (1-800-222-1222)</p>		<p><b>Inactive Ingredients</b> anhydrous citric acid, carboxymethylcellulose sodium, flavors, poloxamer 188, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose</p> <p><b>Questions?</b> call 1-800-343-7805 (toll-free) or 215-273-8755 (collect)</p>											
<p>Active ingredient made in Switzerland  Distributed by: Kenvue Brands LLC  Summit, NJ 07901  © Kenvue Brands LLC 2025  www.zyrtec.com  Pat. www.kenvuepats.com  30056907</p>		 <p>Scan for more</p>											

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/s/  
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