









ZYRTEC Allergy oral solution 1mg/ml

NDA 22155/S029

Draft Drug Facts Label

Drug Facts		Drug Facts (continued)
Active Ingredient <i>(in each 5 mL)</i>	Purpose	
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.		
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 ■ in rare cases, you may experience itching after stopping cetirizine. Consult your healthcare provider if this happens.		
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. (1-800-222-1222)		
		Directions ■ use only with enclosed dosing cup ■ find right dose on chart below ■ mL = milliliter
		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
		Other Information ■ 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
		Inactive Ingredients anhydrous citric acid, carboxymethylcellulose sodium, flavors, poloxamer 188, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose
		Questions? call 1-800-343-7805 (toll-free) or 215-273-8755 (collect)
		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
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/s/

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