

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-155

LABELING

Active ingredient (in each 5 mL teaspoonful): Cetirizine HCl 5 mg

Purpose: Antihistamine

Use: Relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring. **Warnings: Severe Allergy Warning:** Get emergency help immediately if you have hives along with any of the following symptoms: trouble swallowing, dizziness or loss of consciousness, wheezing or tongue swelling in or around mouth, trouble speaking, drooling, wheezing or problems breathing. These symptoms may be signs of anaphylactic shock. This condition can be life threatening, if not treated by a health professional immediately. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later. **Do not use as a substitute for epinephrine.** If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times. **Do not use:** to prevent hives from any known cause such as: foods, insect stings, medicines, latex or rubber gloves because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause. **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. **Asks a doctor or pharmacist before use if you are:** taking tranquilizers or sedatives. When using this product, drowsiness may occur. **Do not use:** if you are drinking alcohol, sedatives, and tranquilizers may increase drowsiness. **Do not use:** if you are 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 symptoms do not improve after 3 days of treatment. **Do not use:** if the hives have lasted more than 6 weeks.

Children's
ZYRTEC
cetirizine HCl
1 mg / mL oral
solution, antihistamine

**24 Relief of
hour ITCHING**

**HIVES
Relief**

6 yrs.
& older

Grape
Syrup

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

Directions: Use only with enclosed dosing cup. Adults and children 6 years and over: 1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours. Adults 65 years and over: 1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) 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°F).

Inactive ingredients: flavors, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate, sodium hydroxide, sugar.

Caution: Do not use if cap is broken or missing. Do not use if contents is opened, or if mechanical impurities are present.

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www.zyrtec.com
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OT/EP

150% For Review Only

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

Directions: Use only with enclosed dosing cup. Adults and children 6 years and over: 1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours. Adults 65 years and over: 1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) 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°F).

Inactive ingredients: flavors, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate, sodium hydroxide, sugar.

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Children's
ZYRTEC
Cetirizine HCl
1 mg / mL oral
solution, antihistamine

**24 Relief of
hour ITCHING**

**HIVES
Relief**

6 yrs.
& older

Grape
Syrup

Actual Size

NEW!

Children's
ZYRTEC

Cetirizine HCl
1 mg /ml oral
solution antihistamine

**24 Relief of
Hour Itching**
Grape
Syrup

RUC XXXXX-XXX-XX

NEW!

Children's
ZYRTEC

Cetirizine HCl
1 mg /ml oral
solution antihistamine

**24 Relief of
Hour Itching**
Grape
Syrup

**6 yrs.
& older**

**Dosing Cup
Included**

Dosing cup should be washed and left to
air dry after each use.

Do not use if carton is opened, or if neckband
imprinted "ZYRTEC" is broken or missing.
See bottom panel for expiration date.

4 FL OZ (118mL)



The makers of ZYRTEC do not make store brand products.
The first dose of this ZYRTEC package is subject to trademark protection.

Drug Facts

Active ingredient (in each 5 mL teaspoonful) Cetirizine HCl 5 mg antihistamine

Uses

relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Warnings

Severe Allergy Warning: Get emergency help immediately if you have hives along with any of the following symptoms:
■ trouble swallowing ■ dizziness or loss of consciousness
■ swelling of tongue ■ swelling in or around mouth
■ trouble speaking ■ drooling
■ wheezing or problems breathing

These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional immediately. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

Not a Substitute for Epinephrine: If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergic symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use

- to prevent hives from any known cause such as:
■ foods ■ insect stings ■ medicines
■ hives when they will not stop hives from occurring.
■ Because this cup will not stop hives from occurring, hives can sometimes be severe. If you do not know the cause of hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.
■ 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.
■ hives that are an unusual color, look, or feel or blistered
■ hives that do not itch

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.

■ symptoms do not improve after 3 days of treatment
■ the hives have lasted more than 6 weeks



NEW!

Children's
ZYRTEC

Cetirizine HCl
1 mg /ml oral
solution antihistamine

Drug Facts (continued)

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 ■ use only with enclosed dosing cup
adults and children
6 years and over
1 teaspoonful (5 mL) or
2 teaspoonfuls (10 mL) once daily
depending upon severity of
symptoms; do not take more than
2 teaspoonfuls (10 mL) at 24 hours.

adults 65 years and over
do not take more than 1 teaspoonful
(5 mL) in 24 hours
ask a doctor

children under 6 years of age
ask a doctor

consumers with liver
or kidney disease

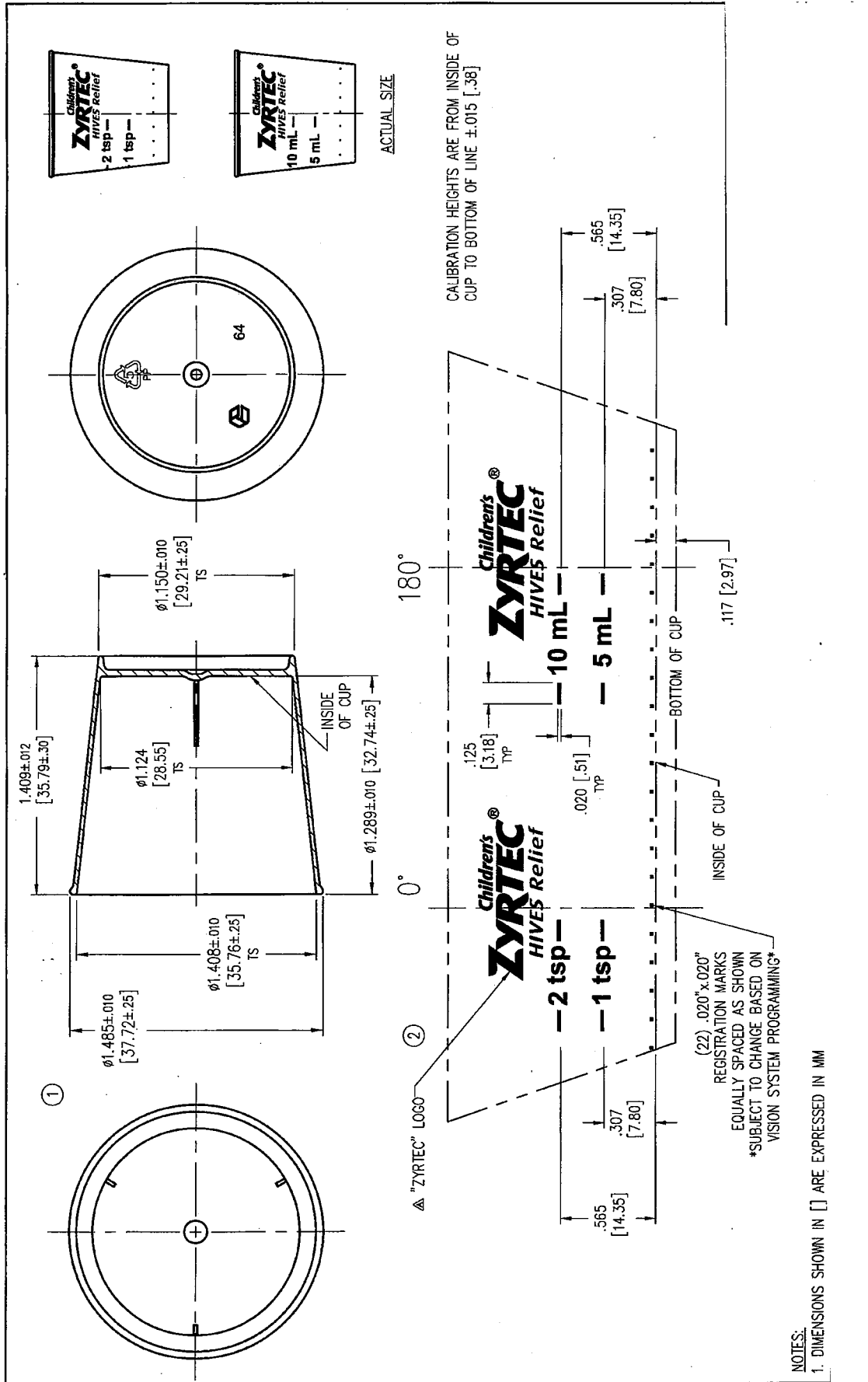
Other information ■ store between 20° to 25°C (68° to 77°F)

Inactive ingredients ■ flavors, citric acid, glycerin,
methylparaben, propylene glycol, propylparaben, purified water,
sodium acetate, sodium hydroxide, sugar

Questions? ■ call 1-800-342-7805

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C100000

A 22-155: Zyrtec (cetirizine HCl 1 mg/mL) Syrup
 Over-the-Counter (OTC) Use
 Amendment to Pending Application



NOTES:
 1. DIMENSIONS SHOWN IN [] ARE EXPRESSED IN MM

COMPANY CONFIDENTIAL

NOTES:

Active ingredient (in each 5 mL teaspoonful) Cetirizine HCl 5 mg

Purpose 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 ■ use only with enclosed dosing cup ■ adults and children 6 years and over: 1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily depending upon severity of symptoms; do not take more than 2 teaspoonfuls (10 mL) in 24 hours. ■ adults 65 years and over: 1 teaspoonful (5 mL) once daily; do not take more than 1 teaspoonful (5 mL) in 24 hours.

Children's ZYRTEC
 (cetirizine HCl)
 1 mg/mL oral solution
 antihistamine
 Indoor & Outdoor Allergies
 21 Hour
 2 yrs. & older
 Grape Syrup

150% For Review Only

Directions ■ children 2 to under 6 years of age: 1/2 teaspoonful (2.5 mL) once daily. If needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or 1/2 teaspoonful (2.5 mL) every 12 hours. Do not give more than 1 teaspoonful (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 ■ store between 20° to 25°C (68° to 77°F)

Inactive ingredients flavors, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate, sodium hydroxide, sugar

Questions? call 1-800-343-7885

Dosing cup should be washed and left to air dry after each use.

Do not use if carton is opened, or if sealband is imprinted "Zyrtec" is broken or missing.

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LOT/EXP

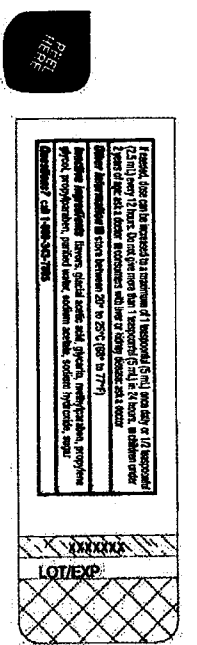
Active ingredient (in each 5 mL teaspoonful) Cetirizine HCl 5 mg

Purpose Antihistamine

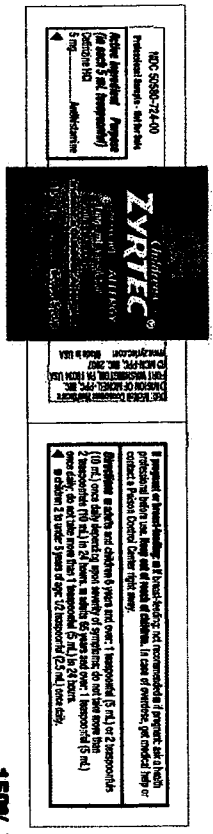
■ children 2 to under 6 years of age: 1/2 teaspoonful (2.5 mL)



Cover Page 1



Base Label
Page 5



Cover Page 1

Page 4

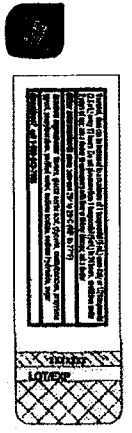
150% For Review Only

Page 3

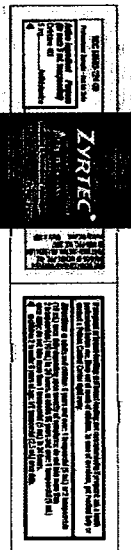
Page 2



Cover Page 1



Base Label
Page 5



Cover Page 1

Page 4

Actual Size

Page 3

Page 2

NEW!

Children's ZYRTEC

Cetirizine HCl
1mg/mL oral solution
antihistamine
Indoor & Outdoor Allergies



NDC 53056-724-10

NEW!

Children's ZYRTEC

Cetirizine HCl
1mg/mL oral solution
antihistamine
Indoor & Outdoor Allergies

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



2 yrs. & older
Grape Syrup

4 FL OZ (118 mL)

Children's Zyrtec
1mg/mL Oral Solution



NEW!

Children's ZYRTEC

Cetirizine HCl
1mg/mL oral solution
antihistamine
Indoor & Outdoor Allergies



NDC 53056-724-10

NEW!

Children's ZYRTEC

Cetirizine HCl
1mg/mL oral solution
antihistamine
Indoor & Outdoor Allergies

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



2 yrs. & older
Grape Syrup

4 FL OZ (118 mL)

Children's Zyrtec
1mg/mL Oral Solution



Drug Facts (continued)

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
● Avoid alcoholic drinks, over-the-counter medicines, and tranquilizers may increase drowsiness.
● Do not drink alcohol while using this product.
● Do not use while 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
● Use only with enclosed dosing cup.
● Adults and children 6 years and over: 1 teaspoonful (5 mL) or 2 teaspoonfuls (10 mL) once daily, depending upon severity of symptoms, do not take more than 2 teaspoonfuls (10 mL) in 24 hours.
● Adults 65 years and over: 1 teaspoonful (5 mL) once daily, do not take more than 1 teaspoonful (5 mL) in 24 hours.
● Children 2 to under 6 years of age: 1/2 teaspoonful (2.5 mL) once daily, if needed, dose can be increased to a maximum of 1 teaspoonful (5 mL) once daily or 1/2 teaspoonful (2.5 mL) every 12 hours. Do not give more than 1 teaspoonful (5 mL) in 24 hours.

Other Information
● Store between 20° to 25° (68° to 77° F).
● Inactive ingredients: flavors, glacial acetic acid, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium acetate, sodium hydroxide, sugar.

Questions? call 1-888-364-1185

Children under 2 years of age: ask a doctor.
Consumers with liver or kidney disease: ask a doctor.

NEW!

Children's ZYRTEC

Cetirizine HCl
1mg/mL oral solution
antihistamine
Indoor & Outdoor Allergies



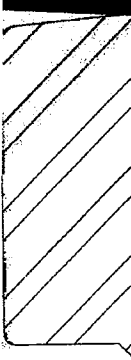
2 yrs. & older
Grape Syrup

Dosing Cup Included

Dosing cup should be washed and left to air dry after each use.

Do not use if carton is opened, or if neckband imprinted "ZYRTEC" is broken or missing. See bottom panel for expiration date.

The makers of Zyrtec® do not make other brand products.
The most direct in this Zyrtec® package is marked "Expiration Date".
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NEW!
Children's
ZYRTEC
 (Cetirizine HCl) ALLERGY
 1 mg/mL oral suspension
 Pediatric Formulation
 Indoor & Outdoor Allergies

TWIN PACK

Children's
ZYRTEC
 (Cetirizine HCl) ALLERGY
 1 mg/mL oral suspension
 Pediatric Formulation
 Indoor & Outdoor Allergies

24 Relief of
 sneezing
 itchy nose
 itchy/watery eyes
 itchy throat or nose

TWIN PACK

Twin Pack contains 2 bottles of 4 fl. oz. (118 mL) each



2 yrs. & older
Grabs Syrup

NEW!
Children's
ZYRTEC
 (Cetirizine HCl) ALLERGY
 1 mg/mL oral suspension
 Pediatric Formulation
 Indoor & Outdoor Allergies

TWIN PACK

Children's
ZYRTEC
 (Cetirizine HCl) ALLERGY
 1 mg/mL oral suspension
 Pediatric Formulation
 Indoor & Outdoor Allergies

24 Relief of
 sneezing
 itchy nose
 itchy/watery eyes
 itchy throat or nose

TWIN PACK
 40.7 fl. oz. Inside



2 yrs. & older
Grabs Syrup

Drug Facts
Active ingredient (in each 5 mL teaspoonful)
 Cetirizine HCl 5 mg
Paracetamol
 100 mg

Uses
 Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 sneezing, runny nose, itchy eyes

Warnings
 Do not use if you have had an allergic reaction to the product or any of its ingredients or to an antihistamine containing hydroxyzine.

When using this product:
 • Do not use if you are taking other antihistamines.
 • Do not drink alcohol while using this product.
 • Do not use if you are taking other sedatives or tranquilizers.
 • Do not use if you are taking other drugs that may interact with this product.

Directions
 • Use only with oral dosing cup.
 • Shake well before use.
 • Spoonful (5 mL) twice daily, or 10 mL (2 teaspoons) twice daily, depending upon severity of symptoms.
 • For children 2 to 5 years of age: 2.5 mL (half teaspoon) twice daily, or 5 mL (1 teaspoon) twice daily, depending upon severity of symptoms.
 • For children 6 to 11 years of age: 5 mL (1 teaspoon) twice daily, or 10 mL (2 teaspoons) twice daily, depending upon severity of symptoms.
 • For children 12 years of age and older: 10 mL (2 teaspoons) twice daily, or 20 mL (4 teaspoons) twice daily, depending upon severity of symptoms.

Other information
 • Contains paracetamol. Avoid alcohol and grapefruit juice while using this product.
 • Contains cetirizine. Avoid grapefruit juice while using this product.
 • Contains cetirizine. Avoid alcohol and grapefruit juice while using this product.

Other information
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Children's
ZYRTEC
 (Cetirizine HCl) ALLERGY
 1 mg/mL oral suspension
 Pediatric Formulation
 Indoor & Outdoor Allergies

24 Relief of
 sneezing
 itchy nose
 itchy/watery eyes
 itchy throat or nose

Dosing Cup Included

Dosing cup should be washed and left in air dry after each use.
 Do not use if carton is opened, or if prebened impregnated ZYRTEC sachet is opened or missing.
 See bottom panel for expiration date.



MISSION 3

INDIEST

Great Taste

NEW!

Children's
ZYRTEC[®]
 ALLERGY
 Cetirizine HCl
 1 mg/mL oral solution
 antihistamine

Indoor & Outdoor Allergies

24 Hour

Drug Facts	Active Ingredient (in each 5 mL teaspoonful) Pyrrolizidine Cetirizine HCl 5 mg	Purpose Antihistamine
(Uses) Zyrtec (oral solution) relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> runny nose itching 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. Ask a doctor about drowsiness if you need a different drug. Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.		
When using this product <ul style="list-style-type: none"> do not drink alcohol do not drink grapefruit juice do not take other antihistamines do not take other allergy medicines do not take other cold or cough medicines do not take other prescription medicines do not take other over-the-counter medicines do not take other prescription medicines do not take other over-the-counter medicines 		
Directions <ul style="list-style-type: none"> Children 6 years and older: 5 mL once daily. Children 2 to 5 years: 2.5 mL once daily. Children 1 to 5 years: 1.25 mL once daily. Children 6 months to 1 year: 1.25 mL once daily. Children 2 to 5 years: 2.5 mL once daily. Children 6 years and older: 5 mL once daily. 		
Drug Facts (continued) <ul style="list-style-type: none"> Keep out of reach of children. If swallowed, do not induce vomiting. Call your doctor or poison control center for more information. Use only as directed. Do not use for longer than 14 days unless your doctor tells you to. See your doctor if you have a severe allergic reaction to this product. See your doctor if you have a severe allergic reaction to this product. See your doctor if you have a severe allergic reaction to this product. See your doctor if you have a severe allergic reaction to this product. 		

Drug Facts (continued)	Other Information
Contains <ul style="list-style-type: none"> Contains 120 mL (4 fl. oz.) of oral solution. Contains 120 mL (4 fl. oz.) of oral solution. Contains 120 mL (4 fl. oz.) of oral solution. Contains 120 mL (4 fl. oz.) of oral solution. 	Keep out of reach of children. If swallowed, do not induce vomiting. Call your doctor or poison control center for more information.
Contains <ul style="list-style-type: none"> Contains 120 mL (4 fl. oz.) of oral solution. Contains 120 mL (4 fl. oz.) of oral solution. Contains 120 mL (4 fl. oz.) of oral solution. Contains 120 mL (4 fl. oz.) of oral solution. 	See your doctor if you have a severe allergic reaction to this product.
Contains <ul style="list-style-type: none"> Contains 120 mL (4 fl. oz.) of oral solution. Contains 120 mL (4 fl. oz.) of oral solution. Contains 120 mL (4 fl. oz.) of oral solution. Contains 120 mL (4 fl. oz.) of oral solution. 	See your doctor if you have a severe allergic reaction to this product.

NEW!

Children's
ZYRTEC[®]
 ALLERGY
 Cetirizine HCl
 1 mg/mL oral solution
 antihistamine

Professional Sample Not for Sale

12 bottles (15 mL) each

NEW!

Children's
ZYRTEC[®]
 ALLERGY
 Cetirizine HCl
 1 mg/mL oral solution
 antihistamine

Indoor & Outdoor Allergies

12 bottles (15 mL) each

Great Taste

upmiss

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Andrea Segal

11/16/2007 12:59:06 PM