

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**19-835/S022**

**21-621/S005**

**LABELING**

Supplemental NDA 19-835/S-022: Zyrtec Tablets (cetirizine HCl 5mg and 10 mg)  
Over-the-Counter (OTC) Use  
Amendment to Pending Application - October 9, 2007

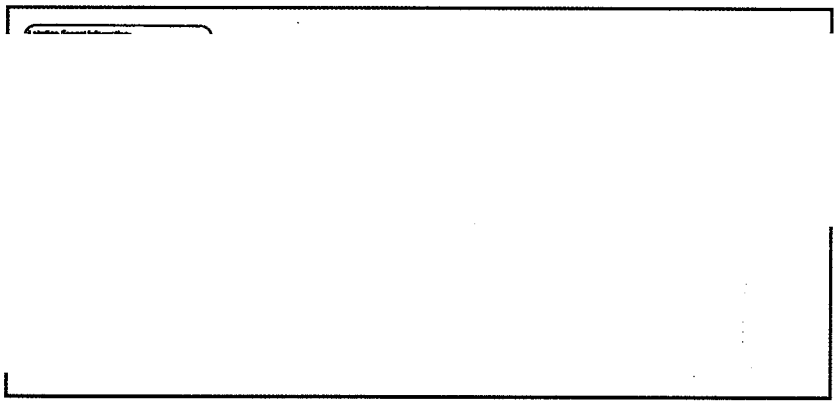
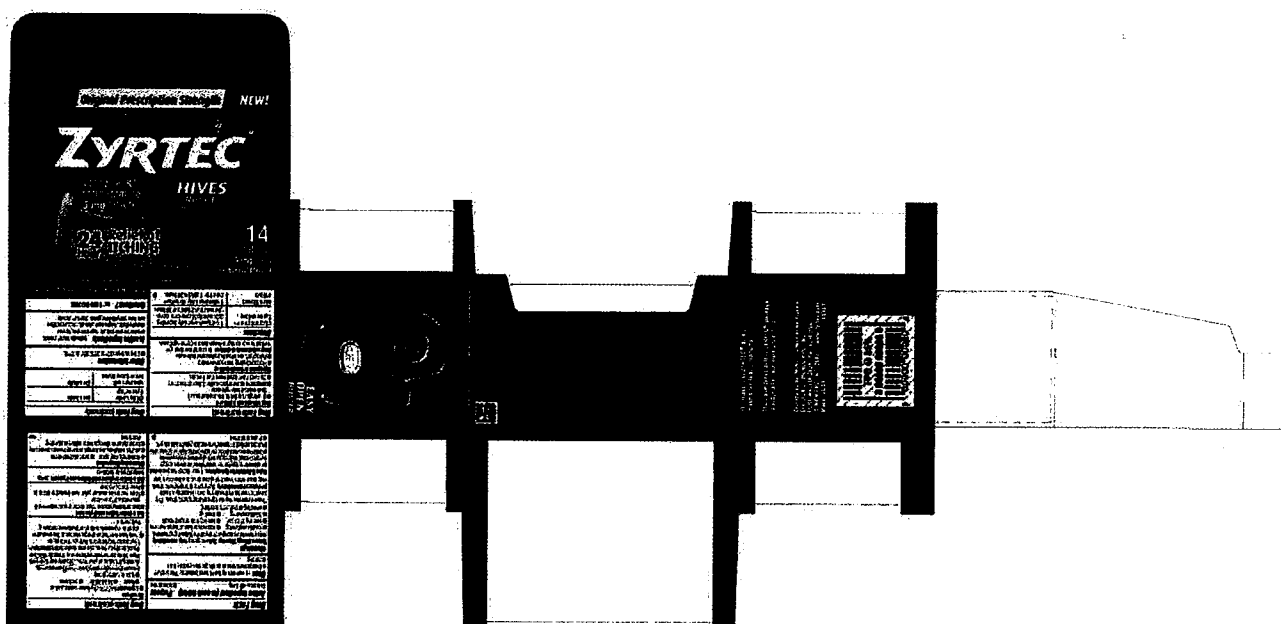
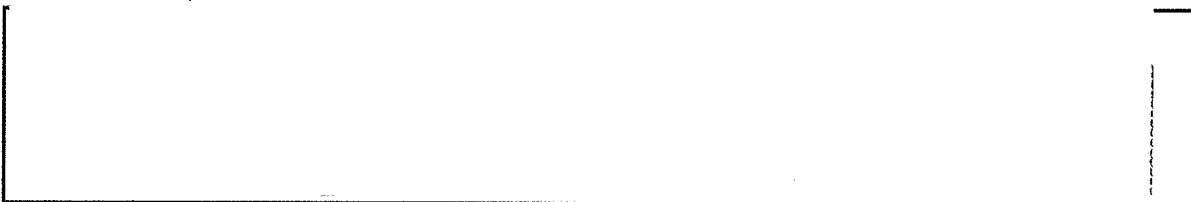
Blister @ 100% Scale



Blister @ 200% Scale



Supplemental NDA 19-835/S-022: Zyrtec Tablets (cetirizine HCl 5mg and 10 mg)  
Over-the-Counter (OTC) Use  
Amendment to Pending Application - October 9, 2007



Supplemental NDA 19-835/S-022: Zyrtec Tablets (cetirizine HCl 5mg and 10 mg)  
Over-the-Counter (OTC) Use  
Amendment to Pending Application - October 9, 2007

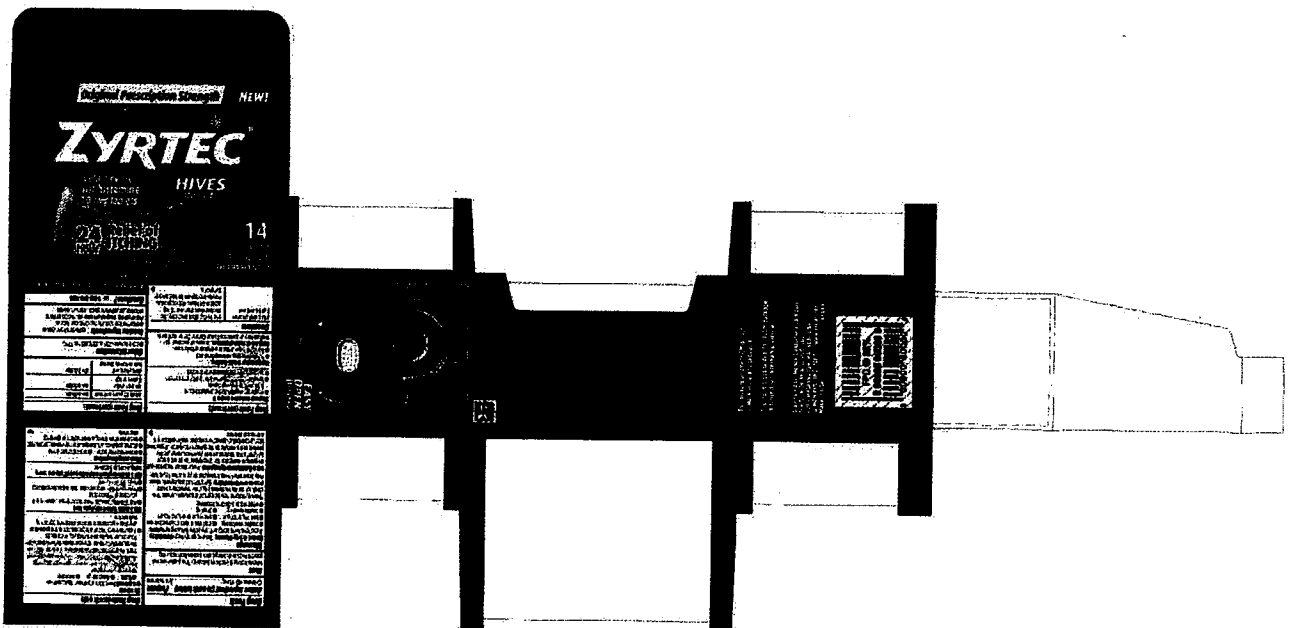
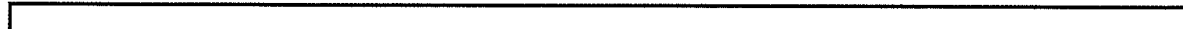
Blister @ 100% Scale



Blister @ 200% Scale



Supplemental NDA 19-835/S-022: Zyrtec Tablets (cetirizine HCl 5mg and 10 mg)  
Over-the-Counter (OTC) Use  
Amendment to Pending Application - October 9, 2007



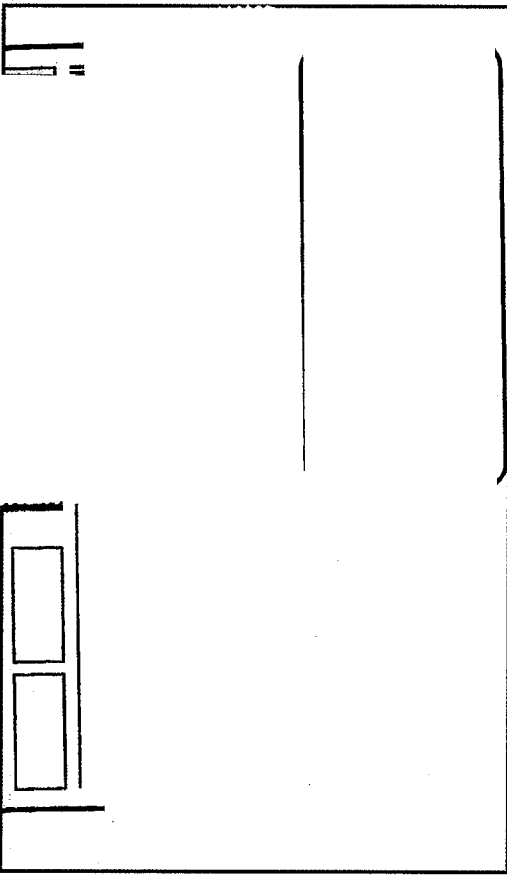
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Supplemental NDA 19-835/S-022: Zyrtec Tablets (cetirizine HCl 5 mg and 10 mg)  
Over-the-Counter (OTC) Use  
Amendment to Pending Application

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<b>Drug Facts</b>	
<b>Active ingredient (in each tablet):</b> Cetirizine HCl 5 mg	<b>Proprietary:</b> Antihistamine
<b>Uses:</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> <li>■ runny nose</li> <li>■ sneezing</li> <li>■ itchy, watery eyes</li> <li>■ itching of the nose or throat</li> </ul>	
<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. <ul style="list-style-type: none"> <li>■ Ask a doctor before use if you have liver or kidney disease.</li> <li>■ Ask a doctor before use if you are taking other drugs.</li> <li>■ Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</li> </ul>	
<b>When using this product:</b> <ul style="list-style-type: none"> <li>■ avoid alcoholic drinks</li> <li>■ drowsiness may occur</li> <li>■ alcohol, sedatives, and tranquilizers may increase drowsiness</li> <li>■ be careful when driving a motor vehicle or operating machinery</li> </ul>	
<b>See you and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</b>	
<b>Directions:</b> <ul style="list-style-type: none"> <li>■ If pregnant or breast-feeding: not recommended</li> <li>■ If pregnant: ask a health professional before use.</li> <li>■ Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</li> </ul>	
<b>Directions:</b> adults and children 6 years and over ages 6-5 years and over children under 6 years of age consumers with liver or kidney disease	1 to 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours. 1 tablet once a day; do not take more than 1 tablet in 24 hours ask a doctor ask a doctor
<b>Other information</b> ■ store between 20° to 25°C (68° to 77°F)	
<b>Inactive ingredients:</b> colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide	
<b>Questions?</b> Call 1-800-543-7885	

TO OPEN: PUSH TABS AT ARROWS - LIFT CARD AT PERFORATIONS

**Do not use if individual blister unit is open or torn.**  
The nature of ZYRTEC® do not make sure hand products.  
The back of the ZYRTEC® package is subject to tamper protection.  
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X000X  
www.zyrtec.com

**NEW!**

**Original Prescription Strength**

# ZYRTEC®

24 TABLETS

Cetirizine HCl/antihistamine  
5 mg tablets

**ALLERGY**

Indoor & Outdoor Allergies

**14**  
Tablets  
5 mg each  
(Individual Blisters)

**EASY OPEN BLISTER**

Submission B

Supplemental NDA 19-835/S-022: Zyrtec Tablets (cetirizine HCl 5 mg and 10 mg)  
Over-the-Counter (OTC) Use  
Amendment to Pending Application

Blister @ 100% Scale



Blister @ 200% Scale





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

# ZYRTEC<sup>®</sup>

## ALLERGY

Cetirizine HCl/  
antihistamine  
10 mg tablets  
30  
Tablets  
10 mg each

**Active ingredient (in each tablet)** Cetirizine HCl 10 mg

**Progress** Antihistamine

It temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: a 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 and alcoholic drinks, alcohol, sedatives, and tranquilizers may increase drowsiness. Be careful when driving a motor vehicle or operating machinery. **Do not use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away. If pregnant or breast-feeding, do not breast-feed; not recommended in 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 15 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. **Consume with food or heavy dietetic:** ask a doctor. **Other information:** Store between 20° to 25°C (68° to 77°F). **Inactive ingredients:** calcium silicate dihydrate, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide. **Questions?** call 1-800-545-7885. **Dist. by:** MICHEL-PRC, INC., FORT WASHINGTON, PA 19134 USA. © MICHEL-PRC, INC. 2007. Made in USA. [www.zyrtec.com](http://www.zyrtec.com) XXXXX

150% For Review Only

**ZYRTEC<sup>®</sup>**  
ALLERGY

Cetirizine HCl/  
antihistamine  
10 mg tablets  
30  
Tablets  
10 mg each

**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 15 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. **Consume with food or heavy dietetic:** ask a doctor. **Other information:** Store between 20° to 25°C (68° to 77°F). **Inactive ingredients:** calcium silicate dihydrate, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide. **Questions?** call 1-800-545-7885. **Dist. by:** MICHEL-PRC, INC., FORT WASHINGTON, PA 19134 USA. © MICHEL-PRC, INC. 2007. Made in USA. [www.zyrtec.com](http://www.zyrtec.com) XXXXX

Actual Size

Submission

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

# ZYRTEC<sup>®</sup>

## ALLERGY

Cetirizine HCl/  
antihistamine  
10 mg tablets **45**  
Tablets  
10 mg each

**Active ingredient (in each tablet):** Antihistamine  
Cetirizine HCl 10 mg. **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, acetaminophen, and tranquilizers may increase drowsiness. Do not drive when driving a motor vehicle or operating machinery. See use and see 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. **Caution:** Patients with liver or kidney disease: ask a doctor. **Other information:** **Keep out of reach of children.** Store at 77°F. **Excipients:** hydroxypropyl methylcellulose, croscarmellose sodium, hypromellose, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide, **Contains?** **cellulose**. **Net Wt. 100 mg (3.527 oz.).** **DCI by MCKEY-PPC, INC., FORT WASHINGTON, PA 19034 USA**  
© MCK-PPC, INC. 2007 [www.zyrtec.com](http://www.zyrtec.com) XXXXX

150% For Review Only

**ZYRTEC<sup>®</sup>**  
ALLERGY

Cetirizine HCl/  
antihistamine  
10 mg tablets **45**  
Tablets  
10 mg each

**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, acetaminophen, and tranquilizers may increase drowsiness. Do not drive when driving a motor vehicle or operating machinery. See use and see a doctor if an allergic reaction to this product occurs. Seek medical help right away if pregnant or breast-feeding. 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. **Caution:** Patients with liver or kidney disease: ask a doctor. **Other information:** **Keep out of reach of children.** Store at 77°F. **Excipients:** hydroxypropyl methylcellulose, croscarmellose sodium, hypromellose, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide, **Contains?** **cellulose**. **Net Wt. 100 mg (3.527 oz.).** **DCI by MCKEY-PPC, INC., FORT WASHINGTON, PA 19034 USA**  
© MCK-PPC, INC. 2007 [www.zyrtec.com](http://www.zyrtec.com) XXXXX

Actual Size

upmissio1

Original Prescription Strength

**NEW!**

**ZYRTEC**<sup>®</sup>

ALLERGY

Cetirizine HCl/  
antihistamine  
10 mg tablets

Indoor & Outdoor Allergies

**24**  
hour

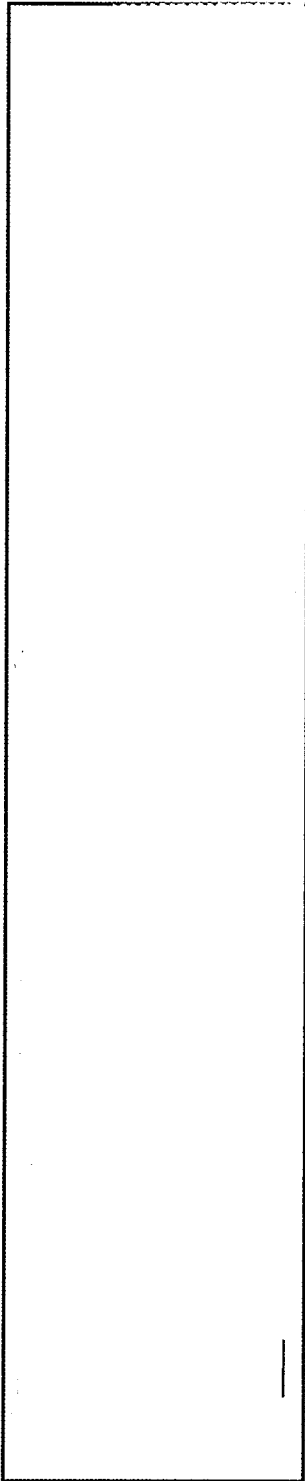
**5** Tablets 10 mg each  
(Individual Blisters)

**EASY  
OPEN  
BLISTER**

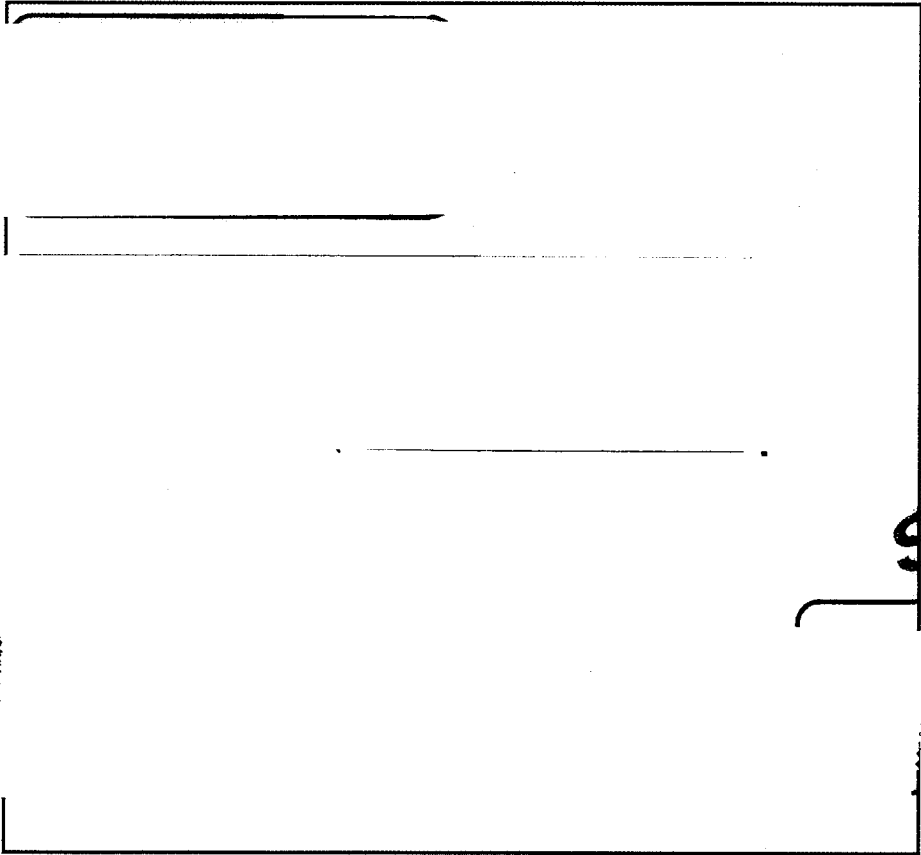
Submission B

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<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient (in each tablet)</b> Cetirizine HCl 10 mg	<b>Purpose</b> Antihistamine	<b>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</b>	
<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		<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. In case of overdose, get medical help or contact a Poison Control Center right away.</b>	
<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>Directions</b> 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.	
<b>TO OPEN:</b> PUSH TAB AT ARROW - LIFT CARD AT PERFORATIONS		<b>Other information</b> ■ store between 20° to 25°C (68° to 77°F).	
<b>Do not use if individual blister unit is open or torn.</b>  The makers of ZYRTEC® do not make store brand products. The trade dress of this ZYRTEC® package is subject to trademark protection.  Distributed by: McNeil Consumer Healthcare DIVISION OF MCNEIL-PPC, INC. FORT WASHINGTON, PA 19034 USA © MCN-PPC, INC. 2007    Made in USA www.zyrtec.com    Patent Pending XXXXX		<b>Inactive ingredients:</b> colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide	
		<b>Questions?</b> call 1-800-343-7085	



**Original Prescription Strength**

**NEW!**

**ZYRTEC<sup>®</sup>**

**24<sup>hour</sup>**

Cetirizine HCl/antihistamine  
10 mg tablets

**ALLERGY**

**Indoor & Outdoor Allergies**

**14**

Tablets  
10 mg each  
(Individual Blisters)

**EASY  
OPEN  
BLISTER**

**Submission B**

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**Drug Facts**

<b>Active Ingredient (in each tablet)</b> Cetirizine HCl 10 mg	<b>Purpose</b> Antihistamine
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**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.

**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.

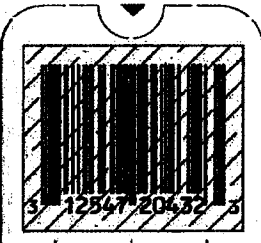
<b>Directions</b>	
adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

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

**Inactive ingredients** colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

**Questions?** call 1-800-343-7885

TO OPEN: PUSH TABS AT ARROWS - LIFT CARD AT PERFORATIONS



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

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XXXXX Patent Pending

Original Prescription Strength

NEW!

**ZYRTEC**<sup>®</sup>

ALLERGY

Cetirizine HCl/  
antihistamine  
10 mg tablets

Indoor & Outdoor Allergies

24  
hour


30 Tablets 10 mg each



Submission B

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<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient (in each tablet)</b> Cetirizine HCl 10 mg		<b>Purpose</b> Antihistamine	
<b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> <li>runny nose</li> <li>sneezing</li> <li>itchy, watery eyes</li> <li>itching of the nose or throat</li> </ul>		<p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p><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>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</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>Directions</b>	
<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>adults and children 6 years and over</p> <p>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.</p>	<p>adults 65 years and over</p> <p>ask a doctor</p>
<b>When using this product</b>		<p>children under 6 years of age</p> <p>ask a doctor</p>	<p>consumers with liver or kidney disease</p> <p>ask a doctor</p>
<ul style="list-style-type: none"> <li>drowsiness may occur</li> <li>alcohol, sodatives, and tranquilizers may increase drowsiness</li> <li>be careful when driving a motor vehicle or operating machinery</li> </ul>		<p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store between 20° to 25°C (68° to 77°F)</li> </ul>	
<b>TO OPEN:</b> PUSH AT ARROWS- LIFT TO OPEN		<p><b>Inactive ingredients</b> colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide</p>	
<p>Do not use if imprinted foil inner seal on bottle is broken or missing.</p> <p>The makers of ZYRTEC® do not make store brand products. The trade dress of this ZYRTEC® package is subject to trademark protection.</p>		<p><b>Questions?</b> call 1-888-343-7805</p>	
<p>Distributed by:          McNeil Consumer Healthcare          DIVISION OF MCNEIL-PPC, INC.          FORT WASHINGTON, PA 19034 USA          © MCN-PPC, INC. 2007 Made in USA          www.zyrtec.com          XXXXX</p>			

11/07/07



Original Prescription Strength

**NEW!**

**ZYRTEC**<sup>®</sup>

ALLERGY

Cetirizine HCl/  
antihistamine  
10 mg tablets

Indoor & Outdoor Allergies

**24**  
hour

**45** Tablets 10 mg each



**Submission B**

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NOTES

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient (in each tablet)</b> Cetirizine HCl 10 mg		<b>Purpose</b> Antihistamine	
<b>Uses</b> temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> <li>■ runny nose</li> <li>■ sneezing</li> <li>■ itchy, watery eyes</li> <li>■ itching of the nose or throat</li> </ul>		<p><b>Warnings</b></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  <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>Directions</b>		<p>if pregnant or breast-feeding:  <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> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
<b>Warnings</b>		<b>Directions</b>	
<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  <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>		<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.</p> <p>adults 65 years and over ask a doctor</p> <p>children under 6 years of age ask a doctor</p> <p>consumers with liver or kidney disease ask a doctor</p>	
<b>Other Information</b>		<b>Other Information</b>	
<p>■ store between 20° to 25°C (68° to 77°F)</p>		<p>■ store between 20° to 25°C (68° to 77°F)</p>	
<b>Inactive ingredients</b>		<b>Inactive ingredients</b>	
colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide		colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide	
<b>Questions?</b> call 1-800-343-7005		<b>Questions?</b> call 1-800-343-7005	


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XXXXX



Original Prescription Strength

NEW!

# ZYRTEC®

Cetirizine HCl/antihistamine  
10 mg tablets

ALLERGY

Indoor & Outdoor Allergies

VALUE PACK  
75  
Tablets

24  
hour

Relief of  
sneezing

runny nose  
Watery Eyes

• Runny Nose

• Itchy Throat or Nose

(1 Bottle of 45  
1 Bottle of 30 tablets)



75 Tablets

10 mg each (contains one bottle of 45 tablets and one bottle of 30 tablets)

n B

Original Prescription Strength

# ZYRTEC<sup>®</sup>

Cetirizine HCl/antihistamine  
10 mg tablets

**ALLERGY**

**Indoor & Outdoor Allergies**

**24  
hour**

runny nose  
itchy, watery eyes  
itchy throat/nose

**Drug Facts**

**Active ingredient (in each tablet)**

Cetirizine HCl 10 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
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- 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

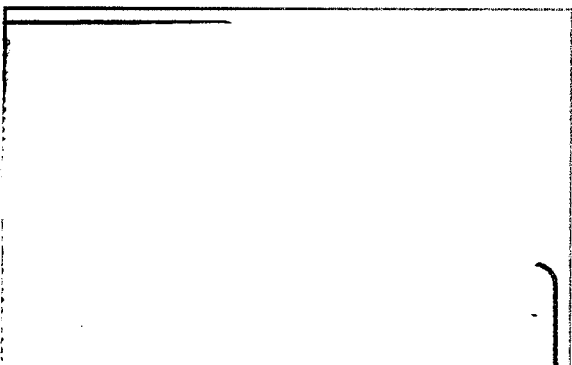
**Other information**

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

**inactive ingredients** colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide



**Questions?** call 1-800-343-7805



10/1 B

NDC 50580 726 03  
NOT FOR RETAIL SALE

Original Prescription Strength

# ZYRTEC<sup>®</sup>

Cetirizine HCl/antihistamine  
10 mg tablets **ALLERGY**

Indoor & Outdoor Allergies

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

**24**  
hour

**1**  
tablet  
10 mg each  
in each blister

**Active Ingredient (in each tablet)**

Cetirizine HCl 10 mg

**Purpose**  
Antihistamine

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.

Use with caution if you have liver or kidney disease. Your doctor should determine if you need a different dose.

Let a doctor or pharmacist before use if you are taking tranquilizers or sedatives, when taking has proved to drowsiness may occur. ■ Avoid alcoholic drinks

■ In 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 the 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. ■ Consult your doctor if symptoms do not improve.

**Other Information** ■ Store between 20° to 25°C (68° to 77°F)

**Inactive Ingredients** ■ colloidal silicon dioxide, croscarmellose sodium, hypromellose, butane monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

**Questions?** call 1-800-346-7005

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Made in USA Patent Pending

XXXXX



EASY OPTM BRAND



24 HOUR

50 Precess of 1 Tablet Per Packet To Help You Breathe Easier

PRE-SAMPLES NOT FOR SALE

# ZYRTEC

Cetirizine HCl/antihistamine  
10 mg tablets  
ALLERGY

Original Prescription Strength

NEW!

# ZYRTEC

Cetirizine HCl/antihistamine  
10mg tablets  
ALLERGY

Indoor & Outdoor Allergies

24 HOUR

Lot No.	Exp. Date	Quantity	Lot No.	Exp. Date	Quantity
10000000000000000000	12/31/10	10000000000000000000	10000000000000000000	12/31/10	10000000000000000000
10000000000000000000	12/31/10	10000000000000000000	10000000000000000000	12/31/10	10000000000000000000
10000000000000000000	12/31/10	10000000000000000000	10000000000000000000	12/31/10	10000000000000000000
10000000000000000000	12/31/10	10000000000000000000	10000000000000000000	12/31/10	10000000000000000000
10000000000000000000	12/31/10	10000000000000000000	10000000000000000000	12/31/10	10000000000000000000
10000000000000000000	12/31/10	10000000000000000000	10000000000000000000	12/31/10	10000000000000000000
10000000000000000000	12/31/10	10000000000000000000	10000000000000000000	12/31/10	10000000000000000000
10000000000000000000	12/31/10	10000000000000000000	10000000000000000000	12/31/10	10000000000000000000
10000000000000000000	12/31/10	10000000000000000000	10000000000000000000	12/31/10	10000000000000000000

PRE-SAMPLES NOT FOR SALE

NEW!

Original Prescription Strength

NEW!

# ZYRTEC

Cetirizine HCl/antihistamine  
10 mg tablets  
ALLERGY

Indoor & Outdoor Allergies

24 Tablets of 10 mg Each

24 Tablets of 10 mg Each

50 Precess of 1 Tablet Per Packet To Help You Breathe Easier

EASY OPTM BRAND

Original Prescription Strength

NEW!

# ZYRTEC

Cetirizine HCl/antihistamine  
10mg tablets  
ALLERGY

Indoor & Outdoor Allergies

24 HOUR

50 Precess of 1 Tablet Per Packet To Help You Breathe Easier

EASY OPTM BRAND

Original Prescription Strength

NEW!

# ZYRTEC

Cetirizine HCl/antihistamine  
10 mg tablets  
ALLERGY

Indoor & Outdoor Allergies

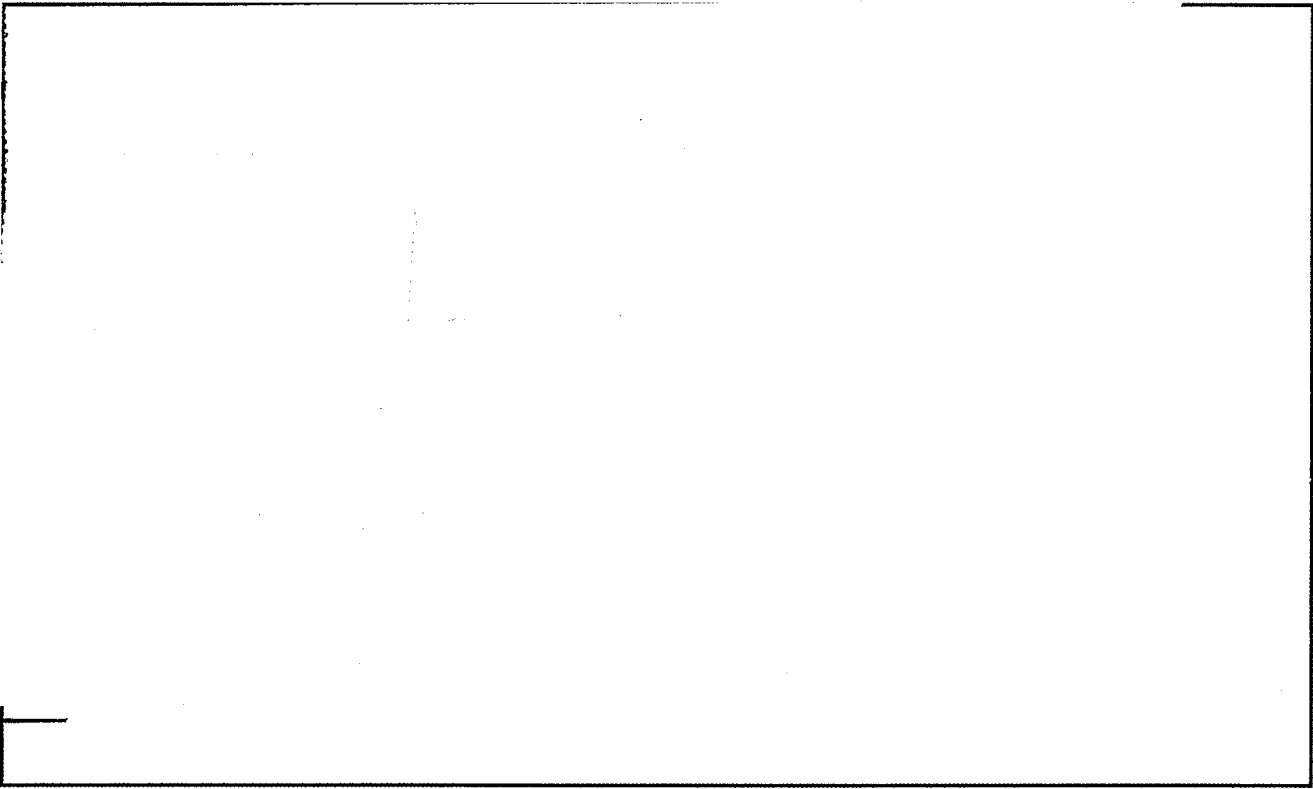
24 Tablets of 10 mg Each

24 Tablets of 10 mg Each

50 Precess of 1 Tablet Per Packet To Help You Breathe Easier

B

<p><b>Children's ZYRTEC®</b> Cetirizine HCl/antihistamine 5 mg chewable tablets</p> <p>Dist. by: Merial Consumer Healthcare DIVISION OF MCHL-PPC, INC. FORT WASHINGTON, PA 19034 USA</p> <p>PEEL BACK/PUSH THROUGH OR USE SCISSORS</p>	<p><b>Children's ZYRTEC®</b> Cetirizine HCl/antihistamine 5 mg chewable tablets</p> <p>Dist. by: Merial Consumer Healthcare DIVISION OF MCHL-PPC, INC. FORT WASHINGTON, PA 19034 USA</p> <p>PEEL BACK/PUSH THROUGH OR USE SCISSORS</p>
<p><b>Children's ZYRTEC®</b> Cetirizine HCl/antihistamine 5 mg chewable tablets</p> <p>Dist. by: Merial Consumer Healthcare DIVISION OF MCHL-PPC, INC. FORT WASHINGTON, PA 19034 USA</p> <p>PEEL BACK/PUSH THROUGH OR USE SCISSORS</p>	<p><b>Children's ZYRTEC®</b> Cetirizine HCl/antihistamine 5 mg chewable tablets</p> <p>Dist. by: Merial Consumer Healthcare DIVISION OF MCHL-PPC, INC. FORT WASHINGTON, PA 19034 USA</p> <p>PEEL BACK/PUSH THROUGH OR USE SCISSORS</p>
<p><b>Children's ZYRTEC®</b> Cetirizine HCl/antihistamine 5 mg chewable tablets</p> <p>Dist. by: Merial Consumer Healthcare DIVISION OF MCHL-PPC, INC. FORT WASHINGTON, PA 19034 USA</p> <p>PEEL BACK/PUSH THROUGH OR USE SCISSORS</p>	<p><b>Children's ZYRTEC®</b> Cetirizine HCl/antihistamine 5 mg chewable tablets</p> <p>Dist. by: Merial Consumer Healthcare DIVISION OF MCHL-PPC, INC. FORT WASHINGTON, PA 19034 USA</p> <p>PEEL BACK/PUSH THROUGH OR USE SCISSORS</p>



**Drug Facts**  
**Active Ingredient (in each chewable tablet)**  
 Cetirizine HCl 5 mg  
**Purpose**  
 (Uses) relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

**Original Prescription Strength**

**NEW!**

**Children's**  
**ZYRTEC**

Cetirizine HCl/  
 antihistamine  
 5 mg chewable tablets

**HIVES**  
 Relief

**24** Relief of  
 hour **ITCHING**

**6 yrs.**  
 & older  
 5 mg each

**Grape**  
**Chewables**

**15** Chewable  
 Tablets 5 mg each



**24** relief of  
 hour **ITCHING**  
 Grape  
 Chewables  
**ZYRTEC**  
 Children's  
 HIVES  
 Relief

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

**Drug Facts (continued)**

**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 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.

■ 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 bruised or blistered ■ hives that do not itch

**Ask a doctor or pharmacist before use if you are taking benzodiazepines 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

■ 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**

■ may be taken with or without water

adults and children 6 years and over 1 to 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.

Do not use if blister unit is open or torn.

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 U.S. Patent No. 6,455,833  
 www.zyrtec.com Made in USA XXXLXV

**Drug Facts (continued)**

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

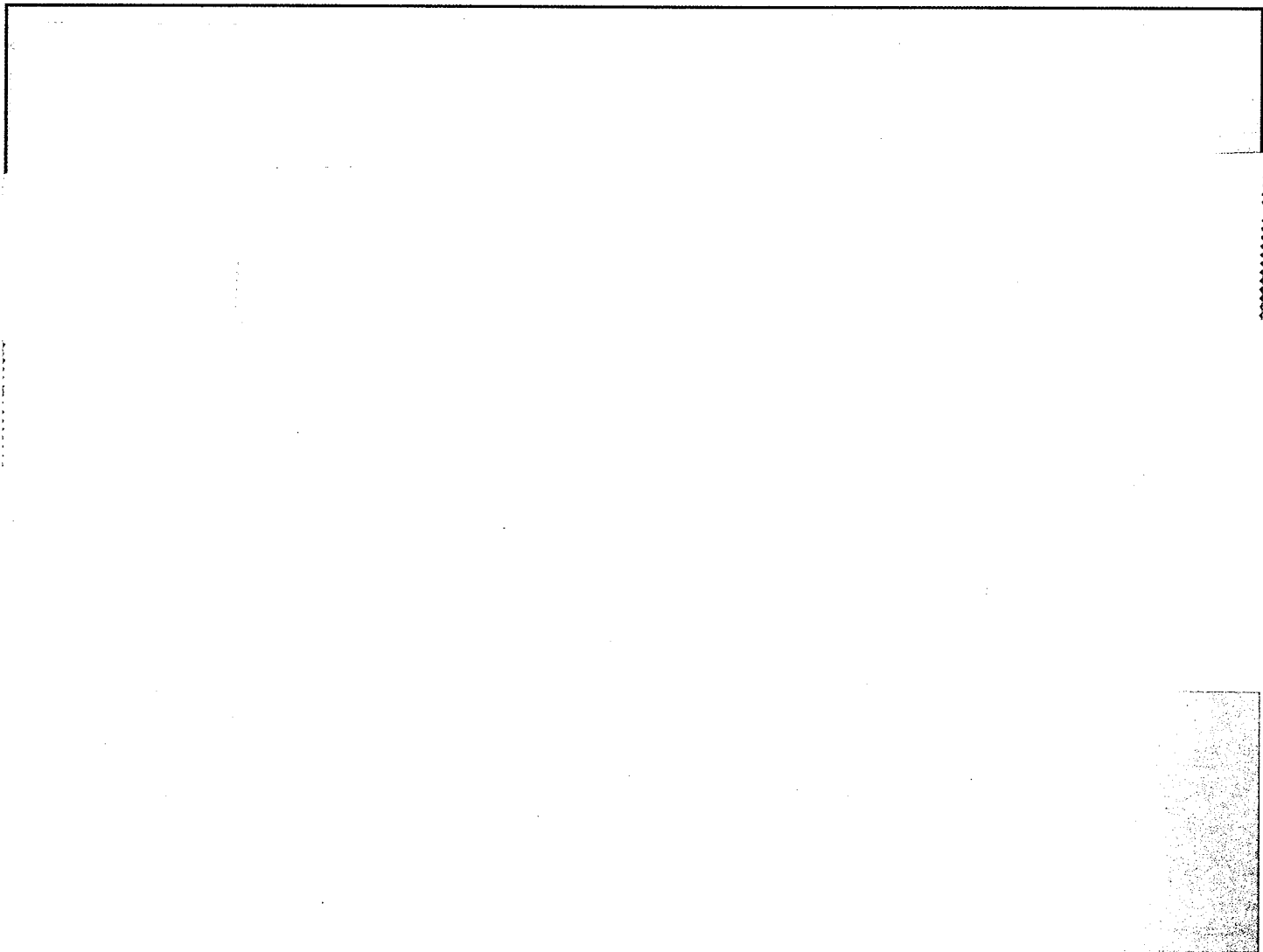
**Inactive ingredients:** acetaminophen, calcium silicate, carmine, colloidal silicon dioxide, croscarmellose sodium, ethyl acetate, FD&C blue no. 2, aluminum lake, inerts, lactose monohydrate, magnesium stearate, mannitol, microcrystalline cellulose, modified croscarmellose sodium

**Questions?** call 1-800-946-7888

Submission A



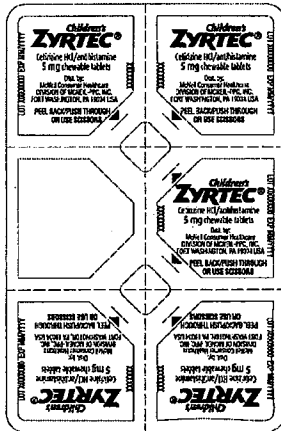
<p><b>Children's ZYRTEC®</b> Cetirizine HCl/antihistamine 10 mg chewable tablets</p> <p>Dist. by: Michael Consumer Healthcare DIVISION OF MICHEL-PPC, INC. FORT WASHINGTON, PA 19034 USA</p> <p>PEEL BACK/PUSH THROUGH OR USE SCISSORS</p>	<p><b>Children's ZYRTEC®</b> Cetirizine HCl/antihistamine 10 mg chewable tablets</p> <p>Dist. by: Michael Consumer Healthcare DIVISION OF MICHEL-PPC, INC. FORT WASHINGTON, PA 19034 USA</p> <p>PEEL BACK/PUSH THROUGH OR USE SCISSORS</p>
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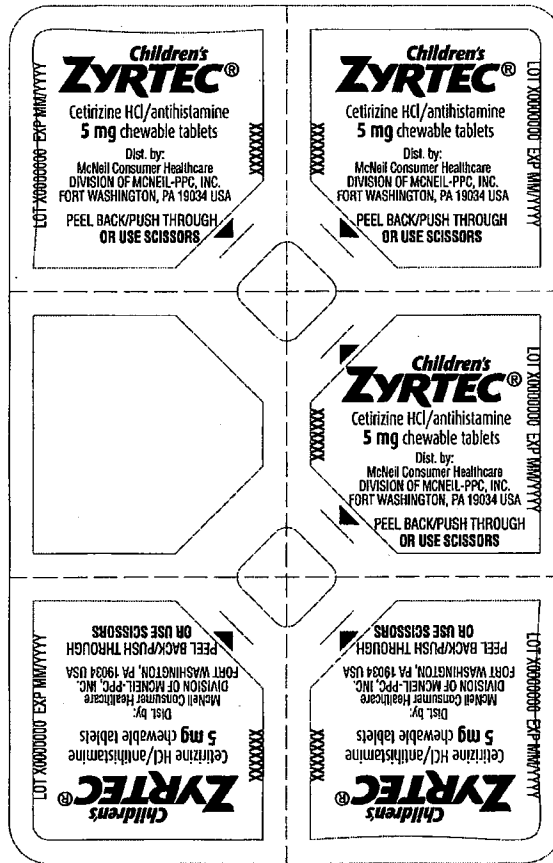


Supplemental NDA 21-621/S-005: Zyrtec Chewable Tablets (cetirizine HCl 5 mg and 10 mg)  
 Over-the-Counter (OTC) Use  
 Amendment to a Pending Application

Blister @ 100% Scale



Blister @ 200% Scale



Submission B

Children's  
**ZYRTEC**<sup>®</sup>  
ALLERGY

NEW!

Children's  
**ZYRTEC**<sup>®</sup>

Cetirizine HCl/  
antihistamine  
5 mg chewable tablets

Indoor/Outdoor Allergies

24  
hour

Grape  
Chewables

5 Chewable  
Tablets 5 mg each

Children's  
**ZYRTEC**<sup>®</sup>  
ALLERGY

**Drug Facts**

**Active Ingredient (in each chewable tablet)** 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, sodas, 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** may be taken with or without water

adults and children 6 years and over 1 to 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°F)

**Inactive Ingredients** acesulfame potassium, betacyclodextrin, calcium silicate, carmine, colloidal silicon dioxide, disodium inosinate/guanylate, ethyl acetate, FD&C blue no. 2 aluminum lake, flavors, lactose monohydrate, magnesium stearate, maltodextrin, mannitol, microcrystalline cellulose, modified cornstarch, sorbitol

**Questions?** call 1-800-343-7000

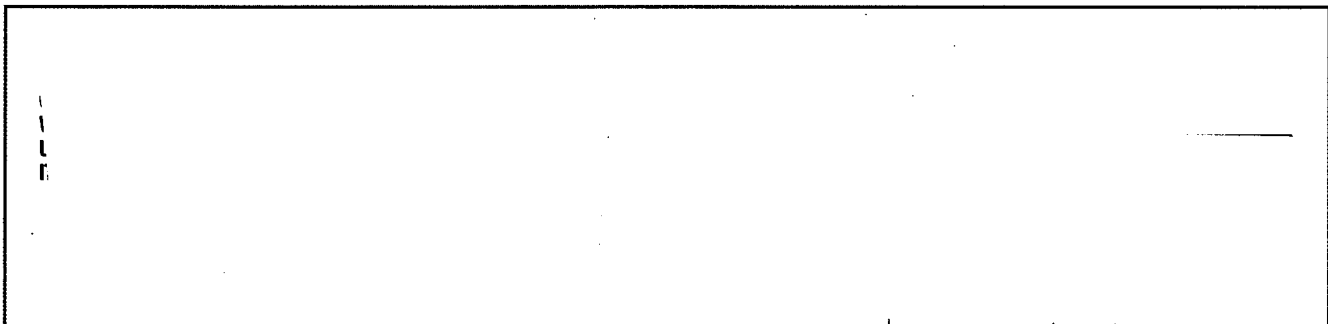
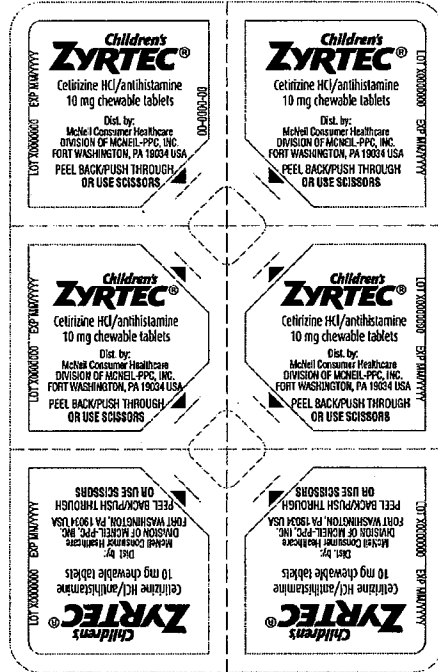
The makers of ZYRTEC<sup>®</sup> do not  
make store brand products.  
The trade dress of this ZYRTEC<sup>®</sup> package  
is subject to trademark protection.

Do not use if blister unit is open or torn.  
Keep out of reach of children. In case of overdose,  
get medical help or contact a Poison Control Center  
right away.  
DIVISION OF MCNEIL-PPC, INC.  
FORT WASHINGTON, PA 19334 USA  
ZYRTEC-PPC, INC. 2007  
U.S. Patent No. 6,555,553  
www.zyrtec.com Made in USA X 100600



Submission B

Supplemental NDA 21-621/S-005: Zyrtec Chewable Tablets (cetirizine HCl 5 mg and 10 mg)  
Over-the-Counter (OTC) Use  
Amendment to a Pending Application



Children's  
**ZYRTEC**<sup>®</sup>  
ALLERGY

Original Prescription Strength

NEW!

Children's  
**ZYRTEC**<sup>®</sup>

Cetirizine HCl/  
antihistamine  
10 mg chewable tablets  
Indoor & Outdoor Allergies

24  
hour

6 yrs.  
& older  
10 mg each

Grape  
Chewables

12 Chewable  
Tablets 10 mg each



Children's  
**ZYRTEC**<sup>®</sup>  
ALLERGY

The makers of Zyrtec do not make steroid brand products.  
The trade dress of this Zyrtec package is subject to trademark protection.

**Drug Facts**

**Active ingredient (in each chewable tablet)** Cetirizine HCl 10 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**  may be taken with or without water

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°F)

**Inactive ingredients** aceulfumate potassium, betacyclodextrin, calcium silicate, carmine, colloidal silicon dioxide, disodium inosinate/guanylate, ethyl acetate, FD&C blue no. 2 aluminum lake, flavors, lactose monohydrate, magnesium stearate, maltodextrin, mannitol, microcrystalline cellulose, modified cornstarch, sorbitol

**Questions?** call 1-888-343-7885

Do not use if blister unit is open or torn.

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Children's  
**ZYRTEC**<sup>®</sup>  
ALLERGY



Division B

Children's  
**ZYRTEC**<sup>®</sup>  
ALLERGY

Grape  
Chewables

Original Prescription Strength

NEW!

Children's  
**ZYRTEC**<sup>®</sup>

Cetirizine HCl/  
antihistamine

10 mg chewable tablets

Indoor & Outdoor Allergies

24  
hour

6 yrs.  
& older  
10 mg each

Grape  
Chewables

24 Chewable  
Tablets 10 mg each

The makers of ZYRTEC<sup>®</sup>  
do not make store brand products.  
The trade dress of this ZYRTEC<sup>®</sup>  
package is subject to  
trademark protection.

Children's  
**ZYRTEC**<sup>®</sup>  
ALLERGY

**Drug Facts**

**Active Ingredient (in each chewable tablet)**  
Cetirizine HCl 10 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**     may be taken with or without water

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°F)

**Inactive ingredients:** acetylsalicylic acid, calcium silicate, carmine, colloidal silicon dioxide, disodium inosinate/guanylate, ethyl acetate, FD&C blue no. 2 aluminum lake, flavors, lactose monohydrate, magnesium stearate, maltodextrin, mannitol, microcrystalline cellulose, modified cornstarch, sorbitol

**Questions?** call 1-800-343-7806

Do not use if blister unit  
is open or torn.

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U.S. Patent No. 6,455,533  
XXXXXX

Children's  
**ZYRTEC**<sup>®</sup>  
ALLERGY



Original Prescription Strength

NDC 50580-722-62

NEW!

Children's  
**ZYRTEC**<sup>®</sup>

24  
hour

Cetirizine HCl/antihistamine **ALLERGY**

10 mg  
chewable  
tablets

Indoor &  
Outdoor  
Allergies

**24**  
Chewable  
Tablets  
10 mg each



B



Original Prescription Strength

NDC 60680-722-82

24  
hour

# Children's ZYRTEC®

Cetirizine HCl/  
antihistamine

ALLERGY

10 mg chewable tablets

Indoor & Outdoor Allergies

6 yrs.  
& older  
10 mg each



Grape  
Chewables

### Drug Facts

#### Active ingredient (in each chewable tablet)

Cetirizine HCl 10 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

■ may be taken with or without water

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°F)

**Inactive ingredients** acesulfame potassium, betacyclodextrin, calcium silicate, carmine, colloidal silicon dioxide, disodium inosinate/guanylate, ethyl acetate, FD&C blue no. 2 aluminum lake, flavors, lactose monohydrate, magnesium stearate, maltodextrin, mannitol, microcrystalline cellulose, modified cornstarch, sorbitol

**Questions?** call 1-800-343-7195

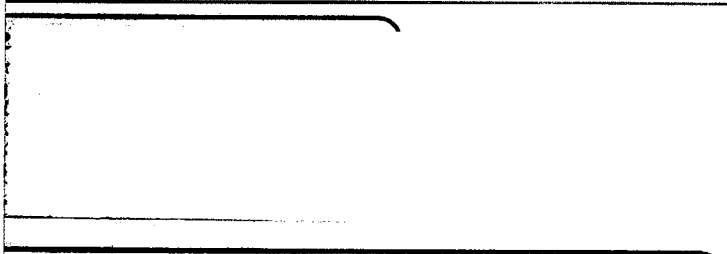


Do not use if blister unit is open or torn.

The makers of ZYRTEC® do not make store brand products.

The trade dress of this ZYRTEC® package is subject to trademark protection.

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/s/

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Andrea Segal

11/16/2007 02:35:38 PM