

NDC 57664-343-15

# Children's Cetrizine Hydrochloride Chewable Tablets, 5 mg

Antihistamine

## HIVES Relief

24 Hour Relief of ITCHING Due to Hives

30 Chewable Tablets

Tutti-frutti Flavor

Open for Full Labeling →

### Drug Facts

**Active ingredient (in each chewable tablet)** Purpose  
Cetrizine hydrochloride 5 mg.....Antihistamine

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



C.S.No. 5839L01  
Iss. 11/07



3 57664 34315 9

DO NOT USE IF IMPRINTED INNER SAFETY SEAL IS TORN OR MISSING

# Proof round 2

GG#:

Part No. & Iss.: 5839L01 Iss. 11/07

Description: Cetrizine Hives Chewable

Final Size: 4.5 x 1.625

mg Size: 5 / Tablet Count: 30

Colors: 3 Black, Process Blue, 2613

UnVarnish Area: 1.444" x 0.25

12/20/07 je

**Warnings**  
Immediately if you have hives along with any of the following symptoms: ● trouble swallowing ● dizziness or loss of consciousness ● difficulty speaking ● swelling of tongue ● trouble speaking ● swelling in or around mouth ● 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

5766434315

**Drug Facts (continued)**  
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

**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

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  
ask a doctor

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** acsulfuram potassium, artificial tutti-frutti flavor, colloidal silicon dioxide, FD&C red, FD&C blue, magnesium oxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, prosover, sodium starch glycolate, talc

5766434315

## This proof is for color break only.

Please refer to The Pantone® Matching System swatches for accurate color. This color WILL NOT MATCH your final printed labels.



Black



Pantone ProcessBlue



Pantone 2613



Pattern Varnish Area



DieCut (does not print)

### Labeling Format Information:

Fonts: Helvetica narrow, bold, oblique, bold oblique	Leading: 6.5pt
Drug Facts: 12pt	Bullets: 5pt
Header: 8pt	Barlines: 1pt
Subheader: 6pt	Headlines: .5pt
Body Text: 6pt	
Drug Facts (continued) 8pt	

Horizontal Scale: 85-100% Average Kerning: 0

NDC 57664-343-16

6 Mts & Older

# Children's Cetrizine Hydrochloride Chewable Tablets, 5 mg

Antihistamine

**HIVES Relief**

24 Hour Relief of ITCHING Due to Hives

100 Chewable Tablets

Tutti-frutti Flavor

Open for Full Labeling →



## Drug Facts

**Active ingredient (in each chewable tablet)** Purpose  
Cetrizine hydrochloride 5 mg.....Antihistamine

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



C.S.No. 5940L01  
Iss.: 11/07

DETROIT, MI 48202

DO NOT USE IF IMPRINTED INNER SAFETY SEAL IS TORN OR MISSING

**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 ● trouble speaking ● swelling of tongue ● trouble breathing ● wheezing or problems breathing ● swelling in or around mouth ● drooling

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

5766434316

**Drug Facts (continued)**  
you are taking tranquilizers or sedatives. **Ask a doctor or pharmacist before use if**

**When using this product**  
● 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

**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

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  
ask a doctor

years of age  
ask a doctor

consumers with liver or kidney disease  
store between 20° to 25°C (68° to 77°F)

**Other information**

**Inactive ingredients** acsulfuram potassium, artificial tutti-frutti flavor, colloidal silicon dioxide, FD&C red, FD&C blue, magnesium oxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, prosover, sodium starch glycolate, talc

## Proof round 2



Black



Pantone ProcessBlue



Pantone 2613



Pattern Varnish Area



DieCut (does not print)

## This proof is for color break only.

Please refer to The Pantone® Matching System swatches for accurate color. This color WILL NOT MATCH your final printed labels.

### Labeling Format Information:

Fonts: Helvetica narrow, bold, oblique, bold oblique  
 Drug Facts: 12pt Leading: 6.5pt  
 Header: 8pt Bullets: 5pt  
 Subheader: 6pt Barlines: 1pt  
 Body Text: 6pt Hairlines: .5pt  
 Drug Facts (continued) 8pt

Horizontal Scale: 85-100%

Average Kerning: 0

GG#: Part No. & Iss.: 5840L01 Iss. 11/07  
 Description: Cetrizine Hives Chewable  
 Final Size: 4.5 x 1.625  
 mg Size: 5 / Tablet Count: 100  
 Colors: 3 Black, Process Blue, 2613  
 UnVarnish Area: 1.444" x 0.25

12/20/07 je

NDC 57664-344-83

# Children's Cetirizine Hydrochloride Chewable Tablets, 10 mg

Antihistamine

## ALLERGY

**24 Hour Relief of**

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

**30 Chewable Tablets**

*Tutti-fruit Flavor*

Open for Full Labeling →

### Drug Facts

**Active ingredient (in each chewable tablet) Purpose**  
Cetirizine hydrochloride 10 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



CARACO  
PHARMACEUTICAL LABORATORIES, LTD.  
TRENTON, NJ 08622

C.S. No.5843L01  
Iss.: 11/07



5766434483

DO NOT USE IF IMPRINTED INNER SAFETY SEAL IS TORN OR MISSING

<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> ● may be taken with or without water adults and children do not take more than one 10 mg tablet once daily; 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>Drug Facts (continued)</b>	

Adhesive

5766434483

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<b>Drug Facts (continued)</b>	
<b>Other Information</b> store between 20° to 25°C (68° to 77°F)	
<b>Inactive Ingredients</b> acetaminophen potassium, artificial fruit-flavor, colloidal silicon dioxide, FD&C red, FD&C blue, magnesium oxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, prosweet, sodium starch glycolate, talc	
<b>Questions or comments?</b> call toll free 1-800-818-4555 weekdays	

5766434483

## Proof round 1

GG#:

Part No. & Iss.: 5843L01 Iss. 11/07

Description: Cetirizine

Final Size: 4.5 x 1.625

mg Size: 10 / Tablet Count: 30

Colors: 3 Black, Process Blue, Rhodamine Red

UnVarnish Area: 1.444" x 0.25

12/19/07 .pd



Black



Pantone ProcessBlue



Pantone Rhodamine Red



Pattern Varnish Area



DieCut [does not print]

### This proof is for color break only.

Please refer to The Pantone® Matching System swatches for accurate color. This color **WILL NOT MATCH** your final printed labels.

#### Labeling Format Information:

Fonts: Helvetica narrow, bold, oblique, bold oblique	6.5pt
Drug Facts:	12pt
Header:	8pt
Bullets:	1pt
Barlines:	6pt
Body Text:	6pt
Drug Facts (continued)	9pt

Horizontal Scale: 85-100%

Average Kerning: 0

NDC 57664-344-88

6 yrs. & Older

# Children's Cetrizine Hydrochloride Chewable Tablets, 10 mg

Antihistamine

**ALLERGY**

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

**100 Chewable Tablets**

*Multi-fruit Flavor*

Open for Full Labeling →

## Drug Facts

**Active ingredient** (in each chewable tablet): Purpose Cetrizine hydrochloride 10 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



3

DO NOT USE IF IMPRINTED INNER SAFETY SEAL IS TORN OR MISSING

Adhesive

<b>Drug Facts</b> (continued)	
<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>Ask a doctor before use if you have</b> liver or kidney disease. Your doctor should determine if you need a different dose. <b>Ask a doctor or pharmacist before use if you are</b> 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>Stop use and ask a doctor if</b> an allergic reaction to this product occurs. Seek medical help right away. <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.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • may be taken with or without water adults and children 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 and over children under 6 ask a doctor years of age consumers with liver or kidney disease	
↑	
5766434488	

<b>Drug Facts</b> (continued)	
<b>Other Information</b> store between 20° to 25° C (68° to 77° F)	
<b>Inactive Ingredients</b> artificial fruit-fluff flavor, colloidal silicon dioxide, FD&C red, FD&C blue, magnesium oxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, prosweet, sodium starch glycolate, talc	
<b>Questions or comments?</b> call toll free 1-800-818-4555 weekdays	

5766434488

## Proof round 1

GG#:

Part No. & Iss.: 5498L01 Iss. 11/07

Description: Cetrizine

Final Size: 4.5 x 1.625

mg Size: 10 / Tablet Count: 100

Colors: 3 Black, Process Blue, Rhodamine Red

UnVarnish Area: 1.444" x 0.25

12/19/07 pdt



Black



Pantone ProcessBlue



Pantone Rhodamine Red



Pattern Varnish Area



DieCut [does not print]

**This proof is for color break only.**

Please refer to The Pantone® Matching System swatches for accurate color. This color **WILL NOT MATCH** your final printed labels.

### Labeling Format Information:

Fonts: Helvetica narrow, bold, oblique, bold oblique	6.5pt
Drug Facts:	12pt
Header:	8pt
Subheader:	6pt
Body Text:	6pt
Drug Facts (continued)	9pt
Horizontal Scale: 85-100%	Average Kerning: 0

NDC 57664-343-83

6 yrs. & older

# Children's Cetirizine Hydrochloride Chewable Tablets, 5 mg

Antihistamine

## ALLERGY

**24 Hour Relief of**  
• Itchy, Watery Eyes • Sneezing • Itchy Throat or Nose  
• Rummy Nose

**30 Chewable Tablets**  
Tutti-Fruiti Flavor

Open for Full Labeling →

### Drug Facts

**Active ingredient** (in each chewable tablet) **Purpose**  
Cetirizine hydrochloride 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



C.S.No. 5838L01  
Iss.: 11/07



5766434383

DO NOT USE IF IMPRINTED INNER SAFETY SEAL IS TORN OR MISSING

<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>Ask a doctor before use if you have liver or kidney disease.</b> Your doctor should determine if you need a different dose.	<b>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</b>	<b>When using this product</b> • drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness	<b>Stop use and ask a doctor if an allergic reaction to this product occurs.</b> Seek medical help right away.	<b>If pregnant or breast-feeding:</b> • breast-feeding: not recommended • If pregnant, ask a health professional before use.	<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	<b>Directions</b> • may be taken with or without water	adults and children 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 ask a doctor	consumers with liver or kidney disease ask a doctor
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Adhesive

1

5766434383

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<b>Drug Facts</b> (continued)	<b>Other Information</b> store between 20° to 25°C (68° to 77°F)	<b>Inactive Ingredients</b> artificial tutti-frutti flavor, colloidal silicon dioxide, FD&C red, FD&C blue, magnesium oxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, prosweet, sodium starch glycolate, talc	<b>Questions or comments?</b> call toll free 1-800-818-4555 weekdays
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## Proof round 1



Black



Pantone ProcessBlue



Pantone 187



Pattern Varnish Area



DieCut [does not print]

### This proof is for color break only.

Please refer to The Pantone® Matching System swatches for accurate color. This color **WILL NOT MATCH** your final printed labels.

#### Labeling Format Information:

<b>Fonts:</b> Helvetica narrow, bold, oblique, bold oblique	<b>Leading:</b> 6.5pt
<b>Drug Facts:</b> 12pt	<b>Bullets:</b> 5pt
<b>Header:</b> 8pt	<b>Barlines:</b> 1pt
<b>Subheader:</b> 6pt	<b>Hairlines:</b> .5pt
<b>Body Text:</b> 6pt	
<b>Drug Facts (continued)</b> 9pt	

Average Kerning: 0

Horizontal Scale: 85-100%

GG#:

Part No. & Iss.: 5838L01 Iss. 11/07

Description: Cetirizine

Final Size: 4.5 x 1.625

mg Size: 5 / Tablet Count: 30

Colors: 3 Black, Process Blue, 187

UnVarnish Area: 1.444" x 0.25

12/19/07 pd

NDC 57664-343-88

# Children's Cetirizine Hydrochloride Chewable Tablets, 5 mg

Antihistamine

**24 Hour** Relief of

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

**100 Chewable Tablets**  
Tutti-frutti Flavor

Open for Full Labeling →



## Drug Facts

**Active ingredient:** (in each chewable tablet) Cetirizine hydrochloride 5 mg.....Antihistamine

**Uses**  
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
• sneezing • itchy, watery eyes  
• runny nose  
• itching of the nose or throat



DO NOT USE IF IMPRINTED INNER SAFETY SEAL IS TORN OR MISSING

Adhesive

<b>Drug Facts</b> (continued)	
<b>Do not use</b> if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.	
<b>Ask a doctor before use</b> if you have liver or kidney disease. Your doctor should determine if you need a different dose.	
<b>Ask a doctor or pharmacist before use</b> 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>Stop use and ask a doctor</b> if an allergic reaction to this product occurs. Seek medical help right away.	
• If pregnant or breast-feeding: not recommended	
• If breast-feeding: ask a health professional before use.	
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • may be taken with or without water	
adults and children	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

5766434388



<b>Drug Facts</b> (continued)	
<b>Other information</b> store between 20° to 25°C (68° to 77°F)	
<b>Inactive ingredients</b> acetylsulfamethoxazole, artificial butyl-fruity flavor, colloidal silicon dioxide, FD&C red, FD&C blue, magnesium oxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, povidone, sodium starch glycolate, talc	
<b>Questions or comments?</b> call toll free 1-800-818-4555 weekdays	

5766434388

## Proof round 1

GG#:

Part No. & Iss.: 5495L01 Iss. 11/07

Description: Cetirizine

Final Size: 4.5 x 1.625

mg Size: 5 / Tablet Count: 100

Colors: 3 Black, Process Blue, 187

UnVarnish Area: 1.444" x 0.25

12/19/07 .pd

## This proof is for color break only.

Please refer to The Pantone® Matching System swatches for accurate color. This color **WILL NOT MATCH** your final printed labels.

### Labeling Format Information:

Fonts: Helvetica narrow, bold, oblique, bold oblique	6.5pt
Drug Facts: 12pt	Leading: 5pt
Header: 8pt	Bullets: 1pt
Subheader: 6pt	Barlines: .5pt
Body Text: 6pt	Hairlines: .5pt
Drug Facts (continued) 9pt	
Horizontal Scale: 85-100% Average Kerning: 0	



Black



Pantone ProcessBlue



Pantone 187



Pattern Varnish Area



DieCut [does not print]

NDC 57664-344-15

6 Mts & Older

# Children's Cetrizine Hydrochloride Chewable Tablets, 10 mg

Antihistamine

**HIVES Relief**

24 Hour Relief of ITCHING Due to Hives

30 Chewable Tablets

Tutti-frutti Flavor

Open for Full Labeling →



## Drug Facts

**Active ingredient (in each chewable tablet)** Purpose  
Cetrizine hydrochloride 10 mg.....Antihistamine

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



C.S. No. 5844L01  
Iss. 11/07

DO NOT USE IF IMPRINTED INNER SAFETY SEAL IS TORN OR MISSING

**Warnings** **Immediate!** If you have hives along with any of the following symptoms: ● trouble swallowing ● dizziness or loss of consciousness ● swelling of tongue ● trouble speaking ● swelling in or around mouth ● 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

5766434415

**Drug Facts (continued)**  
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

**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. 6 years and over do not take more than one 10 mg tablet once daily. adults and children one 10 mg tablet once daily. 6 years and over 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 ask a doctor 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** acsulfuric potassium, artificial tutti-frutti flavor, colloidal silicon dioxide, FD&C red, FD&C blue, magnesium oxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, prosover, sodium starch glycolate, talc

5766434415

## Proof round 2

Black



Pantone ProcessBlue



Pantone 370



Pattern Varnish Area



DieCut (does not print)

## This proof is for color break only.

Please refer to The Pantone® Matching System swatches for accurate color. This color **WILL NOT MATCH** your final printed labels.

### Labeling Format Information:

Fonts: Helvetica narrow, bold, oblique, bold oblique  
 Drug Facts: 12pt      Leading: 6.5pt  
 Header: 8pt      Bullets: 5pt  
 Subheader: 6pt      Barlines: 1pt  
 Body Text: 6pt      Hairlines: .5pt  
 Drug Facts (continued) 8pt

Horizontal Scale: 85-100%

Average Kerning: 0

GG#:

Part No. & Iss.: 5844L01 Iss. 11/07

Description: Cetrizine Hives Chewable

Final Size: 4.5 x 1.625

mg Size: 10 / Tablet Count: 30

Colors: 3 Black, Process Blue, 370

UnVarnish Area: 1.444" x 0.25

12/20/07 je

NDC 57664-344-16

6 Mts & Older

# Children's Cetrizine Hydrochloride Chewable Tablets, 10 mg

Antihistamine

**HIVES Relief**

**24 Hour Relief of ITCHING Due to Hives**

**100 Chewable Tablets**

**Tutti-frutti Flavor**

Open for Full Labeling →

## Drug Facts

**Active ingredient (in each chewable tablet)** Purpose  
Cetrizine hydrochloride 10 mg.....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 ● swelling of tongue ● trouble speaking ● swelling in or around mouth ● 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. 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.

**Ask a doctor before use if you have**  
● this product or any of its ingredients or to an antihistamine containing hydroxyzine. ● 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

**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

**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. 6 years and over do not take more than one 10 mg tablet once daily. adults and children 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 ask a doctor years of age ask a doctor consumers with liver or kidney disease ask a doctor store between 20° to 25°C (68° to 77°F)

**Other information**  
artificial tutti-frutti flavor, colloidal silicon dioxide, FD&C red, FD&C blue, magnesium oxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, proswell, sodium starch glycolate, talc

**Drug Facts (continued)**

**Ask a doctor or pharmacist before use if you are taking** tranquilizers or sedatives. ● alcohol, sedatives, and tranquilizers may increase drowsiness ● be careful when driving a motor vehicle or operating machinery

**When using this product**  
● avoid alcoholic drinks ● drowsiness may occur ● avoid alcoholic drinks

**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

**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. 6 years and over do not take more than one 10 mg tablet once daily. adults and children 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 ask a doctor years of age ask a doctor consumers with liver or kidney disease ask a doctor store between 20° to 25°C (68° to 77°F)

**Other information**  
artificial tutti-frutti flavor, colloidal silicon dioxide, FD&C red, FD&C blue, magnesium oxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch, proswell, sodium starch glycolate, talc

**Drug Facts (continued)**

## Proof round 2



**This proof is for color break only.**  
Please refer to The Pantone® Matching System swatches for accurate color. This color **WILL NOT MATCH** your final printed labels.

**GG#:**  
**Part No. & Iss.:** 5845L01 Iss. 11/07  
**Description:** Cetrizine Hives Chewable  
**Final Size:** 4.5 x 1.625  
**mg Size:** 10 / **Tablet Count:** 100  
**Colors:** 3 Black, Process Blue, 370  
**UnVarnish Area:** 1.444" x 0.25

**Labeling Format Information:**  
**Fonts:** Helvetica narrow, bold, oblique, bold oblique  
**Drug Facts:** 12pt **Leading:** 6.5pt  
**Header:** 8pt **Bullets:** 5pt  
**Subheader:** 6pt **Barlines:** 1pt  
**Body Text:** 6pt **Hairlines:** .5pt  
**Drug Facts (continued)** 8pt  
Horizontal Scale: 85-100%  
Average Kerning: 0

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**Drug Facts (continued)**

**Drug Facts (continued)**

**Drug Facts (continued)**