

NDC 57664-540-83

Open for Full Labeling →

# Cetirizine Hydrochloride Tablets, 5 mg

Antihistamine

**ALLERGY**

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

**30 Tablets**

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

| Drug Facts  |                |
|---|----------------|
| <b>Active ingredient (in each tablet)</b>   | <b>Purpose</b> |
| Cetirizine hydrochloride 5 mg.....  | 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      • sneezing      • itchy, watery eyes</li> <li>• itching of the nose or throat</li> </ul> |                |



C.S.No.5828L01  
Iss. 11/07



|  |   |
|--|---|
| <b>Drug Facts (continued)</b>  |   |
| <b>Warnings</b><br>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  |   |
| • be careful when driving a motor vehicle or operating machinery.  |   |
| <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>  |   |
| • 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>  |   |
| 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  |

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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>   |  |
| hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, titanium dioxide |  |
| <b>Questions or comments?</b>   |  |
| call toll free 1-800-318-4355 weekdays  |  |

## Proof round 1

GG#:

Part No. & Iss.: 5828L01 Iss. 11/07

Description: Cetirizine

Final Size: 4.5 x 1.625

mg Size: 5 / Tablet Count: 30

Colors: 3 Black, Process Blue, 199

UnVarnish Area: 1.444" x 0.25

12/19/07 pd



Black



Pantone ProcessBlue



Pantone 199



Pattern Varnish Area



DieCut [does not print]

## This proof

Please refer to \_\_\_\_\_ 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)                               | 9pt  |            |       |

Horizontal Scale: 85-100%

Average Kerning: 0

NDC 57664-540-88

# Cetirizine Hydrochloride Tablets, 5 mg

Antihistamine

**ALLERGY**

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

**100 Tablets**

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

Open for Full Labeling →

| Drug Facts   |                                 |
|--|---------------------------------|
| <b>Active ingredient</b> (in each tablet)  | <b>Purpose</b>                  |
| Cetirizine hydrochloride 5 mg.....   | Antihistamine                   |
| <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 |



C.S.No.5449L01  
Iss. 11/07



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| Drug Facts (continued)   |   |
|--|---|
| <b>Warnings</b><br>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  |   |
| • be careful when driving a motor vehicle or operating machinery.  |   |
| <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>  |   |
| • 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>  |   |
| 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  |

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| Drug Facts (continued)  |  |
|---|--|
| <b>Other information</b>  |  |
| • store between 20° to 25°C (68° to 77°F)   |  |
| <b>Inactive ingredients</b>   |  |
| hypromellose, magnesium stearate, corn starch, cellulose, polyethylene glycol, polysorbate 80, povidone, titanium dioxide |  |
| <b>Questions or comments?</b>   |  |
| call toll free 1-800-818-4355 weekdays  |  |

## Proof round 1

GG#:

Part No. & Iss.: 5449L01 Iss. 11/07

Description: Cetirizine

Final Size: 4.5 x 1.625

mg Size: 5 / Tablet Count: 100

Colors: 3 Black, Process Blue, 199

UnVarnish Area: 1.444" x 0.25

12/19/07 pd



Black



Pantone ProcessBlue



Pantone 199



Pattern Varnish Area



DieCut [does not print]

## This proof

Please refer to \_\_\_\_\_ 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) | 9pt  |            |       |

Horizontal Scale: 85-100%

Average Kerning: 0

NDC 57664-541-83

# Cetirizine Hydrochloride Tablets, 10 mg

Antihistamine

**ALLERGY**

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

**30 Tablets**

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

Open for Full Labeling →

| Drug Facts   |                                 |
|--|---------------------------------|
| <b>Active ingredient (in each tablet)</b>  | <b>Purpose</b>                  |
| Cetirizine hydrochloride 10 mg.....  | Antihistamine                   |
| <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 |



C.S.No.5833L01  
Iss. 11/07



|   |  |
|---|--|
| <b>Drug Facts (continued)</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>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</b>                                |  |
| <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>   |  |
| 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   |

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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>   |             |
| hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, titanium dioxide | corn starch |
| <b>Questions or comments?</b>   |             |
| call toll free 1-800-818-4555 weekdays  |             |

## Proof round 1

GG#:

Part No. & Iss.: 5833L01 Iss. 11/07

Description: Cetirizine

Final Size: 4.5 x 1.625

mg Size: 10 / Tablet Count: 30

Colors: 3 Black, Process Blue, 288

UnVarnish Area: 1.444" x 0.25

12/19/07 pd



Black



Pantone ProcessBlue



Pantone 288



Pattern Varnish Area



DieCut [does not print]

## This proof

Please refer to 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) | 9pt  |            |       |

Horizontal Scale: 85-100%

Average Kerning: 0

NDC 57664-541-88

Open for Full Labeling →

# Cetirizine Hydrochloride Tablets, 10 mg

Antihistamine

**ALLERGY**

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

**100 Tablets**

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

| Drug Facts   |                      |
|--|----------------------|
| <b>Active ingredient (in each tablet)</b>  | <b>Purpose</b>       |
| Cetirizine hydrochloride 10 mg.....  | Antihistamine        |
| <b>Uses</b>  |                      |
| temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: |                      |
| • runny nose   | • sneezing           |
| • itchy of the nose or throat  | • itchy, watery eyes |



C.S.No.5452L01  
Iss. 11/07



### 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**

- 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

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

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### Drug Facts (continued)

#### Other information

- Store between 20° to 25°C (68° to 77°F)

**Inactive ingredients** corn starch,  
hydroxymethylcellulose, magnesium stearate, microcrystalline  
cellulose, polyethylene glycol, polysorbate 80,  
povidone, titanium dioxide

#### Questions or comments?

call toll free 1-800-818-4555 weekdays

## Proof round 1

GG#:

Part No. & Iss.: 5452L01 Iss. 11/07

Description: Cetirizine

Final Size: 4.5 x 1.625

mg Size: 10 / Tablet Count: 100

Colors: 3 Black, Process Blue, 288

UnVarnish Area: 1.444" x 0.25

12/19/07 pd



Black



Pantone ProcessBlue



Pantone 288



Pattern Varnish Area



DieCut [does not print]

## This proof i

Please refer to 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)                               | 9pt  |            |       |

Horizontal Scale: 85-100%

Average Kerning: 0

NDC 57664-540-15

# Cetirizine Hydrochloride Tablets, 5 mg

Antihistamine

**HIVES Relief**

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

**30 Tablets**

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

Open for Full Labeling →

## Drug Facts

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

### Use

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

**CARACO**  
PHARMACEUTICAL LABORATORIES, LTD.  
DETROIT, MI 48202

C.S.No.5829L01  
Iss. 11/07



NDC 57664-54015-2

### 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 ● 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

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### 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

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

corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, titanium dioxide

# Proof round 3

GG#:

Part No. & Iss.: 5829L01 Iss. 11/07

Description: Cetirizine Hives

Final Size: 4.5 x 1.625

mg Size: 5 / Tablet Count: 30

Colors: 3 Black, Process Blue, 341

UnVarnish Area: 1.444" x 0.25

12/20/07 je

 Black

 Pantone ProcessBlue

 Pantone 341

 Pattern Varnish Area

 DieCut [does not print]

## This proof

Please refer to  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

NDC 57664-540-16

# Cetirizine Hydrochloride Tablets, 5 mg

Antihistamine

**HIVES Relief**

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

**100 Tablets**

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

Open for Full Labeling →

## Drug Facts

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

### Use

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

**CARACO**  
PHARMACEUTICAL LABORATORIES, LTD.  
DETROIT, MI 48202

C.S.No.5830L01  
Iss. 11/07



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### 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 ● 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

### 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

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

corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, poly sorbate 80, povidone, titanium dioxide

# Proof round 3

GG#:

Part No. & Iss.: 5830L01 Iss. 11/07

Description: Cetirizine Hives

Final Size: 4.5 x 1.625

mg Size: 5 / Tablet Count: 100

Colors: 3 Black, Process Blue, 341

UnVarnish Area: 1.444" x 0.25

12/20/07 je

 Black

 Pantone ProcessBlue

 Pantone 341

 Pattern Varnish Area

 DieCut [does not print]

## This proof

Please refer to  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

NDC 57664-541-15

# Cetirizine Hydrochloride Tablets, 10 mg

Antihistamine

**HIVES Relief**

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

**30 Tablets**

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

Open for Full Labeling →

**Drug Facts**

**Active ingredient** (in each tablet)    **Purpose**  
Cetirizine 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.5834L01  
Iss. 11/07



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**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 ● 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

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**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**

|  |  |
|--|--|
| 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** corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, titanium dioxide

## Proof round 4

GG#:  
Part No. & Iss.: 5834L01 Iss. 11/07  
Description: Cetirizine Hives  
Final Size: 4.5 x 1.625  
mg Size: 10 / Tablet Count: 30  
Colors: 3 Black, Process Blue, 241  
UnVarnish Area: 1.444" x 0.25

12/20/07 je

-  **Black**
-  **Pantone ProcessBlue**
-  **Pantone 241**
-  **Pattern Varnish Area**
-  **DieCut** [does not print]

### This proof

Please refer to \_\_\_\_\_ swatches for accurate color. This color **WILL NOT MATCH** your final printed labels.

**Labeling Format Information:**

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

Horizontal Scale: 85-100%

Average Kerning: 0

NDC 57664-541-16

# Cetirizine Hydrochloride Tablets, 10 mg

Antihistamine

**HIVES Relief**

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

**100 Tablets**

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

Open for Full Labeling →

**Drug Facts**  
**Active ingredient** (in each tablet) **Purpose**  
 Cetirizine hydrochloride 10 mg.....Antihistamine

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

**CARACO**  
PHARMACEUTICAL LABORATORIES, LTD.  
DETROIT, MI 48202

C.S.No.5835L01  
Iss. 11/07



3 57664-541-16 6

### 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 ● 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 blistered or blistered  
 ● hives that do not itch

5766454116

5766454116

### 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

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

corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, titanium dioxide

# Proof round 4

GG#:

Part No. & Iss.: 5835L01 Iss. 11/07

Description: Cetirizine Hives

Final Size: 4.5 x 1.625

mg Size: 10 / Tablet Count: 100

Colors: 3 Black, Process Blue, 241

UnVarnish Area: 1.444" x 0.25

12/20/07 je

 Black

 Pantone ProcessBlue

 Pantone 241

 Pattern Varnish Area

 DieCut [does not print]

## This proof

Please refer to  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