

**FINAL PRINTED LABELING**  
**ANDA 78-336**  
**CETIRIZINE TABLETS 5 mg (ALLERGY)**  
**10 - COUNT BOTTLE LABEL**

**FA6T652F1 ELA 17A**

<p>Original Prescription Strength  <b>Cetirizine Hydrochloride</b>  <b>Tablets 5 mg</b>          ANTIHISTAMINE  <b>ALLERGY</b>          10 TABLETS</p>	<p><b>Active ingredient (in each tablet)</b>          Cetirizine HCl 5 mg  <i>Use temporarily relieve these symptoms due to hay fever or other upper respiratory allergies:</i>          ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat  <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. 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. <b>If pregnant or breast-feeding:</b> ■ 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: 1 to 2 tablets once daily depending upon</p>	<p><b>Purpose</b>          Antihistamine  <i>severely 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:</i> ■ store between 20° to 25°C (68° to 77°F) ■ <b>inactive ingredients:</b> corn starch, FD&amp;C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin  <b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.          Do not use if printed foil under cap is broken or missing          DISTRIBUTED BY  <b>PERIGO</b>          ALLEGAN, MI 49010  <b>CODE AREA</b>          ■ no varnish ■ no color          : 6T652 FA F1</p>
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**ACTUAL SIZE**

**TO ARTIST:**  
**DO NOT** use color behind the Part #.  
**DO NOT** change position of part #.

**FA6T652F1 ELA 17A**

<p>Original Prescription Strength  <b>Cetirizine Hydrochloride</b>  <b>Tablets 5 mg</b>          ANTIHISTAMINE  <b>ALLERGY</b>          10 TABLETS</p>	<p><b>Active ingredient (in each tablet)</b>          Cetirizine HCl 5 mg  <i>Use temporarily relieve these symptoms due to hay fever or other upper respiratory allergies:</i>          ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat  <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. 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. <b>If pregnant or breast-feeding:</b> ■ 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: 1 to 2 tablets once daily depending upon</p>	<p><b>Purpose</b>          Antihistamine  <i>severely 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:</i> ■ store between 20° to 25°C (68° to 77°F) ■ <b>inactive ingredients:</b> corn starch, FD&amp;C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin  <b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.          Do not use if printed foil under cap is broken or missing          DISTRIBUTED BY  <b>PERIGO</b>          ALLEGAN, MI 49010  <b>CODE AREA</b>          ■ no varnish ■ no color          : 6T652 FA F1</p>
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**150% FOR REVIEW ONLY**

**FORMAT: MODIFIED**  
**TYPE SIZES:**  
**HEADINGS: 4.5 pt Helvetica Neue 77 Bold Cond. Oblique**  
**SUBHEADINGS: 4.5 pt Helvetica Neue 77 Bold Cond.**  
**TEXT: 4.5 pt Helvetica Neue 57 Cond.**  
**MINIMUM LEADING: 4.6 pt**  
**BULLETS: 3.5 pt Square with 2 spaces between statements**

8

**FINAL PRINTED LABELING**  
**ANDA 78-336**  
**CETIRIZINE TABLETS 5 mg (ALLERGY)**  
**10 - COUNT BOTTLE CARTON**

**EFB 350**  
**FA6T652C1**



**FORMAT: STANDARD**

**TYPE SIZES:**

**TITLE:** 9 pt Helvetica Bold Cond. Italic  
**TITLE (continued):** 8 pt Helvetica Bold Cond. Oblique  
 (continued) 8 pt Helvetica Cond. Medium  
**HEADINGS:** 8 pt Helvetica Bold Cond. Italic  
**SUBHEADINGS:** 6 pt Helvetica Bold Cond.  
**TEXT:** 6 pt Helvetica Cond. Medium  
**LEADING:** 6.5/7.0 pt  
**BULLETS:** 5 pt Square with  
 2 M'S spacing between statements  
**HEAVY LINES:** 1.5 pt  
**HAIRLINES:** 0.5 pt

**FINAL PRINTED LABELING  
ANDA 78-336  
CETIRIZINE TABLETS 5 mg (ALLERGY)  
100 - COUNT BOTTLE LABEL**

**FA6T678F1 ELA 17A**

<p>Original Prescription Strength <b>Cetirizine Hydrochloride</b> <b>Tablets 5 mg</b> ANTIHISTAMINE <b>ALLERGY</b> 100 TABLETS</p>	<p><b>Active ingredient (in each tablet)</b> Cetirizine HCl 5 mg.</p> <p><b>Purpose</b> Antihistamine Used temporarily to relieve these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat.</p> <p><b>Warnings</b> Do not use if you have ever had an allergic reaction to the 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. <b>Directions</b> Adults and children 6 years and over: 1 to 2 tablets once daily depending upon</p>	<p>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. <b>Other information</b> ■ store between 20° to 25°C (68° to 77°F) inactive ingredients: corn starch, FD&amp;C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin. <b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional. Do not use if printed foil under cap is broken or missing.</p>
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**ACTUAL SIZE**

**CODE AREA**  
• no varnish • no color  
: L7L78 FA F1

**TO ARTIST:  
DO NOT use color behind the Part #.  
DO NOT change position of part #.**

**FA6T678F1 ELA 17A**

<p>Original Prescription Strength <b>Cetirizine Hydrochloride</b> <b>Tablets 5 mg</b> ANTIHISTAMINE <b>ALLERGY</b> 100 TABLETS</p>	<p><b>Active ingredient (in each tablet)</b> Cetirizine HCl 5 mg.</p> <p><b>Purpose</b> Antihistamine Used temporarily to relieve these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat.</p> <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. 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. <b>Directions</b> Adults and children 6 years and over: 1 to 2 tablets once daily depending upon</p>	<p>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. <b>Other information</b> ■ store between 20° to 25°C (68° to 77°F) inactive ingredients: corn starch, FD&amp;C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin. <b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional. Do not use if printed foil under cap is broken or missing.</p>
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**BULLETS: 3.5 pt Square with 2 spaces between statements**

10

**EFB 350**  
**FA6T678C1**



**FINAL PRINTED LABELING**  
**ANDA 78-336**  
**CETIRIZINE TABLETS 5 mg (ALLERGY)**  
**100 - COUNT BOTTLE CARTON**

**Drug Facts (continued)**

Stop use and ask a doctor if an allergic reaction occurs. Seek medical help if you experience:

- Irritant or harsh feeling
- Itchiness
- Itching, swelling, or redness of the face, lips, or tongue
- Itching, swelling, or redness of the throat
- Itching, swelling, or redness of the eyes
- Itching, swelling, or redness of the skin
- Itching, swelling, or redness of the mouth
- Itching, swelling, or redness of the nose
- Itching, swelling, or redness of the ears
- Itching, swelling, or redness of the neck
- Itching, swelling, or redness of the chest
- Itching, swelling, or redness of the stomach
- Itching, swelling, or redness of the back
- Itching, swelling, or redness of the arms
- Itching, swelling, or redness of the legs
- Itching, swelling, or redness of the feet
- Itching, swelling, or redness of the hands
- Itching, swelling, or redness of the feet

**Directions**

Swallow tablets whole. Do not crush, chew, or break tablets.

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, in the morning and in the evening

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)

**Drug Facts (continued)**

**Inactive ingredients**

corn starch, PEG 400, PVP, hydroxypropylmethylcellulose, polyethylene glycol, polyvinylpyrrolidone, titanium dioxide, triacetin

**Questions?** If you have questions or concerns about your prescription, ask your pharmacist, doctor or health care professional.

Original Prescription Strength  
**Cetirizine Hydrochloride Tablets 5 mg**  
ANTHISTAMINE  
**ALLERGY**

Indoor & Outdoor Allergies

24 Hour Relief of:

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

100 TABLETS

Do not use if printed expiration date has passed. See back for details.

LOT NO. \_\_\_\_\_  
EXP. DATE \_\_\_\_\_  
CODE AREA \_\_\_\_\_

15 APR 17, 13

**Drug Facts**

**Active ingredient Purpose (in each tablet)**

Cetirizine HCl 5 mg.....Antihistamine

**Uses**

temporarily relieves these symptoms from the common cold or upper respiratory allergies:

- sneezing
- runny nose
- 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 had asthma, especially if you have had asthma in the last 2 weeks, or if you are taking other medicines that may interact with this product.

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

**When using this product**

- Do not drink alcohol while using this product.
- Avoid alcoholic drinks.
- Avoid grapefruit juice while using this product.
- Avoid driving or operating machinery while using this product.

**FORMAT: STANDARD**

**TYPE SIZES:**

**TITLE:** 9 pt Helvetica Bold Cond. Italic  
**TITLE (continued):** 8 pt Helvetica Bold Cond. Oblique (continued) 8 pt Helvetica Cond. Medium  
**HEADINGS:** 8 pt Helvetica Bold Cond. Italic  
**SUBHEADINGS:** 6 pt Helvetica Bold Cond.  
**TEXT:** 6 pt Helvetica Cond. Medium  
**LEADING:** 6.5/7.0 pt  
**BULLETS:** 5 pt Square with 2 MS spacing between statements  
**HEAVY LINES:** 1.5 pt  
**HAIRLINES:** 0.5 pt

Original Prescription Strength  
**Cetirizine Hydrochloride Tablets 5 mg**  
 ANTHISTAMINE  
**ALLERGY**  
 Indoor & Outdoor Allergies  
 24 Hour Relief of:  
 • Sneezing • Runny Nose  
 • Itchy, Watery Eyes  
 • Itchy Throat or Nose  
 1000 TABLETS  
DO NOT USE IF PRINTED  
 DATE OR BATCH NUMBER  
 IS MISSING

**Drug Facts**  
**Active ingredient (in each 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, 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 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**  
 croscarmellose, polyethylene glycol, povidone, titanium dioxide, magnesium stearate, croscarmellose, polyethylene glycol, povidone, titanium dioxide, magnesium stearate

**Questions?** If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

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 DISTRIBUTED BY  
**PERHIGO**  
 ALLSAND, MI 49010  
 CODE AREA  
 1 815 634 1711

FA67693F1 ELA 280

FINAL PRINTED LABELING  
 ANDA 78-336  
 CETIRIZINE TABLETS 5 mg (ALLERGY)  
 1000 - COUNT BOTTLE LABEL

**FORMAT: STANDARD**  
**TYPE SIZES:**  
 TITLE: 10 pt Helvetica Bold Cond. Italic  
 HEADINGS: 8 pt Helvetica Bold Cond. Italic  
 SUBHEADINGS: 6 pt Helvetica Bold Cond.  
 TEXT: 6 pt Helvetica Cond. Medium  
 LEADING: 6.5 pt  
 BULLETS: 5 pt Square with  
 2 M'S spacing between statements  
 HEAVY LINES: 1.5 pt  
 HAIRLINES: 0.5 pt

TO ARTIST:  
 DO NOT use color  
 behind the Part #.  
 DO NOT change  
 position of part #.

**Cetirizine Hydrochloride**  
**Tablets 5 mg**  
 ANTHISTAMINE

Original Prescription Strength

**Cetirizine Hydrochloride**  
**Tablets 5 mg**  
 ANTHISTAMINE

Indoor & Outdoor Allergies

24 Hour Relief of:

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

10 TABLETS

DO NOT USE IF THE BUSTER UNIT IS BROKEN OR TORN

DISTRIBUTED BY  
**3M PERHECO**  
 ALLEGRA, MN 55310

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QUESTIONS? If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

**ALLERGY**

**ALLERGY**

**ALLERGY**

**ALLERGY**

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**ALLERGY**

LTL42 FA C1

**FORMAT: STANDARD**

**TYPE SIZES:**

**TITLE:** 10 pt Helvetica Bold Cond. Oblique

**TITLE (continued):** 8 pt Helvetica Bold Cond. Oblique

**HEADINGS:** 8 pt Helvetica Cond. Medium (continued) 8 pt Helvetica Bold Cond. Oblique

**SUBHEADINGS:** 6 pt Helvetica Bold Cond.

**TEXT:** 6 pt Helvetica Medium Cond.

**LEADING:** 6.5/7.0 pt

**BULLETS:** 5 pt square with 2 MS between statements

**HEAVY LINES:** 1.5 pt

**HAIRLINES:** 0.5 pt

**FINAL PRINTED LABELING  
 ANDA 78-336  
 CETIRIZINE TABLETS 5 mg  
 10-COUNT BLISTER CARD**



FINAL PRINTED LABELING  
 ANDA 78-336  
 CETIRIZINE TABLETS 10 mg (ALLERGY)  
 10 - COUNT BOTTLE LABEL

**FA4H252F1 ELA 17A**

<p>Original Prescription Strength</p> <p><b>Cetirizine Hydrochloride Tablets 10 mg</b></p> <p>ANTIHISTAMINE</p> <p><b>ALLERGY</b></p> <p>10 TABLETS</p>	<p><b>Active ingredient (in each tablet)</b>          Cetirizine HCl 10 mg</p> <p>Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <b>runny nose</b> <b>itching</b> <b>itchy watery eyes</b> <b>itching of the nose or throat</b></p> <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. 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. <b>Directions:</b> Adults and children 6 years and over: one 10 mg tablet once daily; do not take</p>	<p><b>Purpose</b>          Antihistamine</p> <p>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>Other information:</b> Store between 20° to 25°C (68° to 77°F). <b>Inactive ingredients:</b> corn starch, FD&amp;C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin</p> <p><b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</p> <p><b>Do not use if printed foil under cap is broken or missing</b></p> <p>DISTRIBUTED BY  <b>PERRIGO</b>          ALLEGAN, MI 49010</p> <p><b>CODE AREA</b>          • no varnish • no color          : 4H252 FA F1</p>
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**FA4H252F1 ELA 17A**

<p>Original Prescription Strength</p> <p><b>Cetirizine Hydrochloride Tablets 10 mg</b></p> <p>ANTIHISTAMINE</p> <p><b>ALLERGY</b></p> <p>10 TABLETS</p>	<p><b>Active ingredient (in each tablet)</b>          Cetirizine HCl 10 mg</p> <p>Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <b>runny nose</b> <b>itching</b> <b>itchy watery eyes</b> <b>itching of the nose or throat</b></p> <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. 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. <b>Directions:</b> Adults and children 6 years and over: one 10 mg tablet once daily; do not take</p>	<p><b>Purpose</b>          Antihistamine</p> <p>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>Other information:</b> Store between 20° to 25°C (68° to 77°F). <b>Inactive ingredients:</b> corn starch, FD&amp;C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin</p> <p><b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</p> <p><b>Do not use if printed foil under cap is broken or missing</b></p> <p>DISTRIBUTED BY  <b>PERRIGO</b>          ALLEGAN, MI 49010</p> <p><b>CODE AREA</b>          • no varnish • no color          : 4H252 FA F1</p>
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**BULLETS: 3.5 pt Square with 2 spaces between statements**



FINAL PRINTED LABELING  
 ANDA 78-336  
 CETIRIZINE TABLETS 10 mg (ALLERGY)  
 100 - COUNT BOTTLE LABEL

FA4H278F1 ELA 17A

<p>Original Prescription Strength  <b>Cetirizine Hydrochloride Tablets 10 mg</b>          ANTIHISTAMINE  <b>ALLERGY</b>          100 TABLETS</p>	<p><b>Active ingredient (in each tablet)</b>          Cetirizine HCl 10 mg.</p> <p><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</p> <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. 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. <b>Directions</b> Adults and children 6 years and over: one 10 mg tablet once daily; do not take</p>	<p><b>Purpose</b> Antihistamine</p> <p><b>Other information</b> 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>Other information</b> ■ store between 20° to 25°C (68° to 77°F)</p> <p><b>Inactive ingredients</b> corn starch, FD&amp;C blue #1, hydroxytoluene, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin</p> <p><b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</p> <p>Do not use if printed foil under cap is broken or missing</p> <p>DISTRIBUTED BY  <b>PERRIGO</b>          ALLEGAN, MI 49010</p> <p><b>CODE AREA</b>          ■ no varnish ■ no color          : 4H278 FA F1</p>
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ACTUAL SIZE

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 DO NOT change position of part #.

FA4H278F1 ELA 17A

<p>Original Prescription Strength  <b>Cetirizine Hydrochloride Tablets 10 mg</b>          ANTIHISTAMINE  <b>ALLERGY</b>          100 TABLETS</p>	<p><b>Active ingredient (in each tablet)</b>          Cetirizine HCl 10 mg.</p> <p><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</p> <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. 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. <b>Directions</b> Adults and children 6 years and over: one 10 mg tablet once daily; do not take</p>	<p><b>Purpose</b> Antihistamine</p> <p><b>Other information</b> 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>Other information</b> ■ store between 20° to 25°C (68° to 77°F)</p> <p><b>Inactive ingredients</b> corn starch, FD&amp;C blue #1, hydroxytoluene, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin</p> <p><b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</p> <p>Do not use if printed foil under cap is broken or missing</p> <p>DISTRIBUTED BY  <b>PERRIGO</b>          ALLEGAN, MI 49010</p> <p><b>CODE AREA</b>          ■ no varnish ■ no color          : 4H278 FA F1</p>
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150% FOR REVIEW ONLY

**FORMAT: MODIFIED**

**TYPE SIZES:**

**HEADINGS: 4.5 pt Helvetica Neue 77 Bold Cond. Oblique**

**SUBHEADINGS: 4.5 pt Helvetica Neue 77 Bold Cond.**

**TEXT: 4.5 pt Helvetica Neue 57 Cond.**

**MINIMUM LEADING: 4.6 pt**

**BULLETS: 3.5 pt Square with 2 spaces between statements**

17

**FINAL PRINTED LABELING**  
**ANDA 78-336**  
**CETIRIZINE TABLETS 10 mg (ALLERGY)**  
**100 - COUNT BOTTLE CARTON**

**EFB 350**  
**FA4H278C1**



**FORMAT: STANDARD**  
**TYPE SIZES:**  
**TITLE: 9 pt Helvetica Bold Cond. Italic**  
**TITLE (continued): 8 pt Helvetica Bold Cond. Oblique (continued) 8 pt Helvetica Cond. Medium**  
**HEADINGS: 8 pt Helvetica Bold Cond. Italic**  
**SUBHEADINGS: 6 pt Helvetica Bold Cond.**  
**TEXT: 6 pt Helvetica Cond. Medium**  
**LEADING: 6.5 pt**  
**BULLETS: 5 pt Square with 2 M'S spacing between statements**  
**HEAVY LINES: 1.5 pt**  
**HAIRLINES: 0.5 pt**



Original Prescription Strength  
**Cetirizine Hydrochloride**  
**Tablets 10 mg**  
 ANTIHISTAMINE  
**ALLERGY**  
 Indoor & Outdoor Allergies  
 24 Hour Relief of:  
 • Sneezing • Runny Nose  
 • Itchy, Watery Eyes  
 • Itchy Throat or Nose  
 DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING  
**1000 TABLETS**

FA4H293F1 ELA 28D

FINAL PRINTED LABELING  
 ANDA 78-336  
 CETIRIZINE TABLETS 10 mg (ALLERGY)  
 1000 - COUNT BOTTLE LABEL

<b>Drug Facts</b>	<b>Active ingredient (in each tablet)</b> Cetirizine HCl 10 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</li> <li>sneezing</li> <li>itchy, watery eyes</li> <li>itching of the nose or throat</li> </ul>	
<b>Warnings</b> <ul style="list-style-type: none"> <li>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.</li> <li>Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.</li> <li>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</li> <li>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> </li> <li>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</li> <li>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> </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: 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>Other Information</b> ■ store between 20° to 25° C (68° to 77° F)	
<b>Inactive ingredients</b> corn starch, FD&C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin	
<b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.	



DISTRIBUTED BY  
**PERFIGO**  
 ALLEGAN, MI 48810

**CODE AREA**  
 10 mg tablets - red color  
 10 mg tablets - white color  
 10 mg tablets - white color

TO ARTIST:  
 DO NOT use color behind the Part #.  
 DO NOT change position of part #.

**FORMAT: STANDARD**  
**TYPE SIZES:**  
 TITLE: 10 pt Helvetica Bold Cond. Italic  
 HEADINGS: 8 pt Helvetica Bold Cond. Italic  
 SUBHEADINGS: 6 pt Helvetica Bold Cond.  
 TEXT: 6 pt Helvetica Cond. Medium  
 LEADING: 6.5 pt  
 BULLETS: 5 pt Square with  
 2 M'S spacing between statements  
 HEAVY LINES: 1.5 pt  
 HAIRLINES: 0.5 pt



FINAL PRINTED LABELING  
ANDA 78-336  
CETIRIZINE TABLETS 10 mg  
7-COUNT BLISTER CARD



**Perrigo's Final Printed Labeling (HIVES RELIEF)**

This section contains the following components:

- Perrigo's final printed labeling for Cetirizine HCl 5 mg Tablets
  - 10-count bottle label
  - 10-count bottle carton
  - 100-count bottle label
  - 100-count bottle carton
  - 1000-count bottle label (no carton)
  - 10-count blister carton
  - 10-count blister card
  
- Perrigo's final printed labeling for Cetirizine HCl 10 mg Tablets
  - 10-count bottle label
  - 10-count bottle carton
  - 100-count bottle label
  - 100-count bottle carton
  - 1000-count bottle label (no carton)
  - 7-count blister carton
  - 7-count blister card

Note: With the exception of net content and product identification (i.e. UPC number, bar code, etc.), the container labels and blister pack carton labels are identical for the size counts listed above.

**FINAL PRINTED LABELING  
ANDA 78-336  
CETIRIZINE TABLETS 5 mg (HIVES)  
10 - COUNT BOTTLE LABEL**

FA94352F1 5" x 2"

<p>Original Prescription Strength</p> <p><b>Cetirizine Hydrochloride Tablets 5 mg</b></p> <p>ANTIHISTAMINE</p> <p><b>HIVES RELIEF</b></p> <p>10 TABLETS</p>	<p><b>Active Ingredient (in each tablet)</b> Cetirizine HCl 5 mg.</p> <p><b>Uses</b> relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.</p> <p><b>Warnings Severe Allergy Warning:</b> 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. <b>Not a Substitute for Epinephrine.</b> 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.</p> <p><b>Do not use</b> ■ 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 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.</p>	<p><b>Purpose</b> Antihistamine</p> <p><b>Stop use and ask a doctor if</b> ■ 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. <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. <b>Other information</b> ■ store between 20° to 25°C (68° to 77°F) <b>Inactive ingredients</b> corn starch, FD&amp;C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin. <b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</p>
	<p><b>Do not use if printed foil under cap is broken or missing</b></p> <p>DISTRIBUTED BY <b>PEREGO</b> ALLEGAN, MI 48801</p> <p><b>CODE AREA</b> no varnish • no color 1-94352 FA F1</p>	

ACTUAL SIZE

TO ARTIST:  
DO NOT use color  
below the Part #.  
DO NOT change  
position of part #.

FA94352F1 5" x 2"

<p>Original Prescription Strength</p> <p><b>Cetirizine Hydrochloride Tablets 5 mg</b></p> <p>ANTIHISTAMINE</p> <p><b>HIVES RELIEF</b></p> <p>10 TABLETS</p>	<p><b>Active ingredient (in each tablet)</b> Cetirizine HCl 5 mg.</p> <p><b>Uses</b> relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.</p> <p><b>Warnings Severe Allergy Warning:</b> 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. <b>Not a Substitute for Epinephrine.</b> 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.</p> <p><b>Do not use</b> ■ 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 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.</p>	<p><b>Purpose</b> Antihistamine</p> <p><b>Stop use and ask a doctor if</b> ■ 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. <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. <b>Other information</b> ■ store between 20° to 25°C (68° to 77°F) <b>Inactive ingredients</b> corn starch, FD&amp;C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin. <b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</p>
	<p><b>Do not use if printed foil under cap is broken or missing</b></p> <p>DISTRIBUTED BY <b>PEREGO</b> ALLEGAN, MI 48801</p> <p><b>CODE AREA</b> no varnish • no color 1-94352 FA F1</p>	

150% FOR REVIEW ONLY

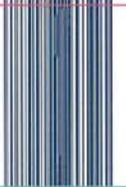
**FORMAT: MODIFIED**  
**TYPE SIZES:**  
**HEADINGS: 4.8 pt Helvetica Neue 77 Bold Cond. Oblique**  
**SUBHEADINGS: 4.8 pt Helvetica Neue 77 Bold Cond.**  
**TEXT: 4.8 pt Helvetica Neue 57 Cond.**  
**MINIMUM LEADING: 5.2 pt**  
**BULLETS: 3.8 pt Square with 2 spaces between statements**

23

12-17-07

FINAL PRINTED LABELING  
 ANDA 78-336  
 CETIRIZINE TABLETS 5 mg (HIVES)  
 10 - COUNT BOTTLE CARTON

**EFB 350**  
**FA94352C1**

		<p><b>Drug Facts</b>  <b>Active ingredient (in each tablet)</b>          Cetirizine HCl 5 mg ..... Antihistamine</p> <p><b>Purpose</b>          Antihistamine</p> <p><b>Uses</b>          Relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.</p> <p><b>Warnings</b>  <b>Severe Allergy Warning:</b> Get emergency help immediately if you have hives along with any of the following symptoms: ▶</p>									
<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>liver or kidney disease. Your doctor should determine if you need a different dose.</li> <li>hives that are an unusual color, look bruised or blistered</li> <li>hives that do not itch</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</b></p> <p><b>When using this product</b></p> <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>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>an allergic reaction to this product occurs. Seek medical help right away.</li> <li>symptoms do not improve after 3 days of treatment</li> <li>the hives have lasted more than 6 weeks</li> </ul> <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. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ▶</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <table border="1"> <tr> <td>adults and children 6 years and over</td> <td>1 to 2 tablets once daily depending upon severity of symptoms; do not take more than 2 tablets in 24 hours</td> </tr> <tr> <td>adults 65 years and over</td> <td>1 tablet once a day; do not take more than 1 tablet in 24 hours</td> </tr> <tr> <td>children under 6 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with liver or kidney disease</td> <td>ask a doctor</td> </tr> </table> <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> <p><b>Inactive ingredients</b> corn starch, FD&amp;C blue #1, hydroxymethylcellulose, lactose, magnesium stearate, polydimethylsiloxane, polyethylene glycol, povidone, titanium dioxide, triacetin</p> <p><b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</p>	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	<p>Original Prescription Strength</p> <p><b>Cetirizine Hydrochloride Tablets 5 mg</b></p> <p>ANTIHISTAMINE</p> <p><b>HIVES RELIEF</b></p> <p>24 Hour Relief of itching due to hives</p> <p>10 TABLETS</p> <p>DO NOT USE IF PRINTED FOLLOWS UNDER CAP IS BROKEN OR MISSING</p>  <p>LOT NO. _____</p> <p>EXP. _____</p> <p><b>CODE AREA</b></p> <p>17N350 FA 03</p>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>trouble swallowing</li> <li>dizziness or loss of consciousness</li> <li>swelling of tongue</li> <li>swelling in or around mouth</li> <li>trouble speaking</li> <li>drooling</li> <li>whistling or problems breathing</li> </ul> <p>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.</p> <p><b>Not a Substitute for Epinephrine.</b> 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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>to prevent hives from any known cause such as:           <ul style="list-style-type: none"> <li>foods</li> <li>insect stings</li> <li>medicines</li> <li>latex or rubber gloves</li> </ul> </li> </ul> <p>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. ▶</p>
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										
		 <p>LOT NO. _____</p> <p>EXP. _____</p> <p><b>CODE AREA</b></p> <p>17N350 FA 03</p>									

**FORMAT: STANDARD**

**TYPE SIZES:**

**TITLE:** 9 pt Helvetica Bold Cond. Oblique

**TITLE (continued):** 8 pt Helvetica Bold Cond. Oblique

**(continued):** 8 pt Helvetica Cond. Medium

**HEADINGS:** 8 pt Helvetica Bold Cond. Oblique

**SUBHEADINGS:** 6 pt Helvetica Bold Cond.

**TEXT:** 6 pt Helvetica Cond. Medium

**MINIMUM LEADING:** 6.5 pt

**BULLETS:** 5 pt Square with 2 M'S spacing between statements

**HEAVY LINES:** 1.5 pt

**HAIRLINES:** 0.5 pt

**FINAL PRINTED LABELING  
ANDA 78-336  
CETIRIZINE TABLETS 5 mg (HIVES)  
100 - COUNT BOTTLE LABEL**

**FA94378F1 5" x 2"**

<p>Original Prescription Strength</p> <p><b>Cetirizine Hydrochloride Tablets 5 mg</b></p> <p>ANTIHISTAMINE</p> <p><b>HIVES RELIEF</b></p> <p>100 TABLETS</p>	<p><b>Active ingredient (in each tablet)</b> Cetirizine HCl 5 mg.</p> <p><b>Uses</b> relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.</p> <p><b>Warnings: Severe Allergy Warning:</b> 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. <b>Not a Substitute for Epinephrine.</b> 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.</p> <p><b>Do not use</b> ■ 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. <b>Ask a doctor before use if you have</b> ■ 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. <b>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives. 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.</p>	<p><b>Purpose</b> Antihistamine</p> <p><b>Stop use and ask a doctor if</b> ■ 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: ■ 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.</p> <p><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.</p> <p><b>Other information</b> ■ store between 20° to 25°C (68° to 77°F)</p> <p><b>Inactive ingredients:</b> corn starch, FD&amp;C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin</p> <p><b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</p> <p><small>Do not use if printed full under cap is broken or missing</small></p>
	<p>DISTRIBUTED BY <b>PERGIGO</b> ALLEGAN, MI 49010</p> <p><b>CODE AREA</b> • no varnish • no color 1 94378 FA F1</p>	

**ACTUAL SIZE**

**TO ARTIST:  
DO NOT use color  
behind the Part #.  
DO NOT change  
position of part #.**

**FA94378F1 5" x 2"**

<p>Original Prescription Strength</p> <p><b>Cetirizine Hydrochloride Tablets 5 mg</b></p> <p>ANTIHISTAMINE</p> <p><b>HIVES RELIEF</b></p> <p>100 TABLETS</p>	<p><b>Active ingredient (in each tablet)</b> Cetirizine HCl 5 mg.</p> <p><b>Uses</b> relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.</p> <p><b>Warnings: Severe Allergy Warning:</b> 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. <b>Not a Substitute for Epinephrine.</b> 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.</p> <p><b>Do not use</b> ■ 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. <b>Ask a doctor before use if you have</b> ■ 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. <b>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives. 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.</p>	<p><b>Purpose</b> Antihistamine</p> <p><b>Stop use and ask a doctor if</b> ■ 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: ■ 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.</p> <p><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.</p> <p><b>Other information</b> ■ store between 20° to 25°C (68° to 77°F)</p> <p><b>Inactive ingredients:</b> corn starch, FD&amp;C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin</p> <p><b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</p> <p><small>Do not use if printed full under cap is broken or missing</small></p>
	<p>DISTRIBUTED BY <b>PERGIGO</b> ALLEGAN, MI 49010</p> <p><b>CODE AREA</b> • no varnish • no color 1 94378 FA F1</p>	

**150% FOR REVIEW ONLY**

**FORMAT: MODIFIED**  
**TYPE SIZES:**  
**HEADINGS: 4.8 pt Helvetica Neue 77 Bold Cond. Oblique**  
**SUBHEADINGS: 4.8 pt Helvetica Neue 77 Bold Cond.**  
**TEXT: 4.8 pt Helvetica Neue 57 Cond.**  
**MINIMUM LEADING: 5.2 pt**  
**BULLETS: 3.8 pt Square with 2 spaces between statements**

25

FINAL PRINTED LABELING  
 ANDA 78-336  
 CETIRIZINE TABLETS 5 mg (HIVES)  
 100 - COUNT BOTTLE CARTON

**EFB 350**  
**FA94378C1**





**Drug Facts**  
**Active ingredient (in each tablet)**  
 Cetirizine HCl 5 mg ..... Antihistamine

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

**Warnings**  
**Severe Allergy Warning:** Get emergency help immediately if you have hives along with any of the following symptoms: ▶

**EFB 350**  
**FA94378C1**

**Drug Facts (continued)**

- 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 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. ▶

**Drug Facts (continued)**

**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
children under 6 years of age 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, FD&C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, Xelatin

**Questions?** If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

Original Prescription Strength

**Cetirizine Hydrochloride Tablets 5 mg**

ANTIHISTAMINE

**HIVES RELIEF**

24 Hour Relief of itching due to hives

100 TABLETS

DO NOT USE IF PRINTED FEEL, TASTE, CAPS, BROKEN OR MISSING



0 00000 00000 0

LOT NO. **CODE AREA**

EXP.

174378 PA 03

**Drug Facts (continued)**

- 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. ▶

**FORMAT: STANDARD**

**TYPE SIZES:**

**TITLE:** 9 pt Helvetica Bold Cond. Oblique

**TITLE (continued):** 8 pt Helvetica Bold Cond. Oblique

**(continued):** 9 pt Helvetica Cond. Medium

**HEADINGS:** 8 pt Helvetica Bold Cond. Oblique

**SUBHEADINGS:** 6 pt Helvetica Bold Cond.

**TEXT:** 6 pt Helvetica Cond. Medium

**MINIMUM LEADING:** 6.5 pt

**BULLETS:** 5 pt Square with 2 M'S spacing between statements

**HEAVY LINES:** 1.5 pt

**HAIRLINES:** 0.5 pt

24

12-17-07





FINAL PRINTED LABELING  
ANDA 78-336  
CETIRIZINE TABLETS 5 mg  
10-COUNT BLISTER CARD



**FINAL PRINTED LABELING  
ANDA 78-336  
CETIRIZINE TABLETS 10 mg (HIVES)  
10- COUNT BOTTLE LABEL**

**FA83852F1 5" X 2"**

Original Prescription Strength

## Cetirizine Hydrochloride Tablets 10 mg

ANTIHISTAMINE

**HIVES RELIEF**

**10 TABLETS**

**Active Ingredient (in each tablet)**  
Cetirizine HCl 10 mg.

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

**Warnings: Severe Allergy Warning:** Get emergency help immediately if you have hives along with any of the following symptoms: ■ trouble swallowing ■ dizziness or loss of consciousness ■ swelling of tongue ■ swelling in or around mouth ■ trouble speaking ■ drooling ■ wheezing or problems breathing. These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional immediately. Symptoms of anaphylactic shock may occur when first exposed 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 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: use 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, FD&C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin

**Questions?** If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

Do not use if printed foil under cap is broken or missing

DISTRIBUTED BY

PERRIGO

ALLEGAN, MI 49010

**CODE AREA**

• no varnish • no color

: 83852 FA F1

**ACTUAL SIZE**

**TO ARTIST:  
DO NOT use color  
behind the Part #.  
DO NOT change  
position of part #.**

**FA83852F1 5" X 2"**

Original Prescription Strength

## Cetirizine Hydrochloride Tablets 10 mg

ANTIHISTAMINE

**HIVES RELIEF**

**10 TABLETS**

**Active Ingredient (in each tablet)**  
Cetirizine HCl 10 mg.

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

**Warnings: Severe Allergy Warning:** Get emergency help immediately if you have hives along with any of the following symptoms: ■ trouble swallowing ■ dizziness or loss of consciousness ■ swelling of tongue ■ swelling in or around mouth ■ trouble speaking ■ drooling ■ wheezing or problems breathing. These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional immediately. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later. **Not a Substitute for Epinephrine.** If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe 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 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, FD&C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin

**Questions?** If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

Do not use if printed foil under cap is broken or missing

DISTRIBUTED BY

PERRIGO

ALLEGAN, MI 49010

**CODE AREA**

• no varnish • no color

: 83852 FA F1

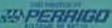
**150% FOR REVIEW ONLY**

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TYPE SIZES:  
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Cond. Oblique  
SUBHEADINGS: 4.8 pt Helvetica Neue 77  
Bold Cond.  
TEXT: 4.8 pt Helvetica Neue 57 Cond.  
LEADING: 5.2 pt  
BULLETS: 3.8 pt Square with  
2 spaces between statements**

30

FINAL PRINTED LABELING  
 ANDA 78-336  
 CETIRIZINE TABLETS 10 mg (HIVES)  
 10- COUNT BOTTLE CARTON

**EFB 350**  
**FA83852C1**

		<p><b>Drug Facts</b>  <b>Active ingredient (in each tablet)</b>          Cetirizine HCl 10 mg      Antihistamine</p> <p><b>Uses</b>          relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.</p> <p><b>Warnings</b>  <b>Severe Allergy Warning:</b> Get emergency help immediately if you have hives along with any of the following symptoms: ▶</p>	
<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.</li> <li>liver or kidney disease. Your doctor should determine if you need a different dose.</li> <li>hives that are an unusual color, look bruised or blistered</li> <li>hives that do not itch</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</b></p> <p><b>When using this product</b></p> <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>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>an allergic reaction to this product occurs. Seek medical help right away.</li> <li>symptoms do not improve after 3 days of treatment</li> <li>the hives have lasted more than 6 weeks</li> </ul> <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><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. ▶</p>	<p><b>Drug Facts (continued)</b></p> <p><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.</p> <p>ask a doctor</p> <p>children under 6 years of age      ask a doctor</p> <p>ask a doctor</p> <p>consumers with liver or kidney disease      ask a doctor</p> <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> <p><b>Inactive ingredients:</b> corn starch, FD&amp;C blue #1, hydroxypropylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin</p> <p><b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</p> <p></p>	<p>Original Prescription Strength</p> <p><b>Cetirizine Hydrochloride Tablets 10 mg</b>          ANTIHISTAMINE</p> <p><b>HIVES RELIEF</b></p> <p>24 Hour Relief of itching due to hives</p> <p>10 TABLETS</p> <p>DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING</p> <p>LOT NO.          EXP. <b>CODE AREA</b></p> <p>FA83852C1</p>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>trouble swallowing</li> <li>dizziness or loss of consciousness</li> <li>swelling of tongue</li> <li>swelling in or around mouth</li> <li>trouble speaking</li> <li>drooling</li> <li>wheezing or problems breathing</li> </ul> <p>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. <b>Not a Substitute for Epinephrine.</b> 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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>to prevent hives from any known cause such as:</li> <li>foods</li> <li>insect stings</li> <li>medicines</li> <li>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.</li> </ul>
		 <p>0 00000 00000 0</p>	

**FORMAT: STANDARD**

**TYPE SIZES:**

**TITLE:** 9 pt Helvetica Bold Cond. Oblique

**TITLE (continued):** 8 pt Helvetica Bold Cond. Oblique (continued) 8 pt Helvetica Cond. Medium

**HEADINGS:** 8 pt Helvetica Bold Cond. Oblique

**SUBHEADINGS:** 6 pt Helvetica Bold Cond.

**TEXT:** 6 pt Helvetica Cond. Medium

**MINIMUM LEADING:** 6.5 pt

**BULLETS:** 5 pt Square with 2 M'S spacing between statements

**HEAVY LINES:** 1.5 pt

**HAIRLINES:** 0.5 pt

**FINAL PRINTED LABELING  
ANDA 78-336  
CETIRIZINE TABLETS 10 mg (HIVES)  
100 - COUNT BOTTLE LABEL**

**FA83878F1 5" X 2"**

Original Prescription Strength

**Cetirizine Hydrochloride Tablets 10 mg**

ANTIHISTAMINE

**HIVES RELIEF**

100 TABLETS

**Active Ingredient (in each tablet)**  
Cetirizine HCl 10 mg.

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

**Warnings Severe Allergy Warning:** Get emergency help immediately if you have hives along with any of the following symptoms: ■ trouble swallowing ■ dizziness or loss of consciousness ■ swelling of tongue ■ swelling in or around mouth ■ trouble speaking ■ drooling ■ wheezing or problems breathing. These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional immediately. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later. **Not a Substitute for Epinephrine.** If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe 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 causes 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 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, 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, FD&C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin

**Questions?** If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

**Do not use if printed foil under cap is broken or missing**

DISTRIBUTED BY  
**PERRIGO**  
LESLIE, MI 48040

**CODE AREA**  
• no varnish • no color  
: 83878 FA F1

**ACTUAL SIZE**

**TO ARTIST:  
DO NOT use color  
behind the Part #.  
DO NOT change  
position of part #.**

**FA83852F1 5" X 2"**

Original Prescription Strength

**Cetirizine Hydrochloride Tablets 10 mg**

ANTIHISTAMINE

**HIVES RELIEF**

100 TABLETS

**Active Ingredient (in each tablet)**  
Cetirizine HCl 10 mg.

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

**Warnings Severe Allergy Warning:** Get emergency help immediately if you have hives along with any of the following symptoms: ■ trouble swallowing ■ dizziness or loss of consciousness ■ swelling of tongue ■ swelling in or around mouth ■ trouble speaking ■ drooling ■ wheezing or problems breathing. These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional immediately. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later. **Not a Substitute for Epinephrine.** If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe 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 causes 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 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, 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, FD&C blue #1, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin

**Questions?** If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

**Do not use if printed foil under cap is broken or missing**

DISTRIBUTED BY  
**PERRIGO**  
ALLEGAN, MI 49010

**CODE AREA**  
• no varnish • no color  
: 83878 FA F1

**150% FOR REVIEW ONLY**

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TYPE SIZES:  
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SUBHEADINGS: 4.8 pt Helvetica Neue 77 Bold Cond.  
TEXT: 4.8 pt Helvetica Neue 57 Cond.  
LEADING: 5.2 pt  
BULLETS: 3.8 pt Square with 2 spaces between statements**

32

FINAL PRINTED LABELING  
 ANDA 78-336  
**CETIRIZINE TABLETS 10 mg (HIVES)**  
 100 - COUNT BOTTLE CARTON

**EFB 350**  
**FA83878C1**

		<p><b>Drug Facts</b>  <b>Active ingredient (in each tablet)</b> Purpose          Cetirizine HCl 10 mg Antihistamine</p> <p><b>Uses</b>          relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.</p> <p><b>Warnings</b>  <b>Severe Allergy Warning:</b> Get emergency help immediately if you have hives along with any of the following symptoms:</p>									
<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.</li> <li>Ask a doctor before use if you have           <ul style="list-style-type: none"> <li>liver or kidney disease. Your doctor should determine if you need a different dose.</li> <li>hives that are an unusual color, look bruised or blistered</li> <li>hives that do not itch</li> </ul> </li> <li>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</li> </ul> <p><b>When using this product</b></p> <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>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>an allergic reaction to this product occurs. Seek medical help right away.</li> <li>symptoms do not improve after 3 days of treatment</li> <li>the hives have lasted more than 6 weeks</li> </ul> <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><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <table border="1"> <tr> <td>adults and children 6 years and over</td> <td>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.</td> </tr> <tr> <td>adults 65 years and over</td> <td>ask a doctor</td> </tr> <tr> <td>children under 6 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with liver or kidney disease</td> <td>ask a doctor</td> </tr> </table> <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> <p><b>Inactive ingredients:</b> corn starch, FD&amp;C blue #1, hydroxypropylcellulose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin</p> <p><b>Questions?</b> If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</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.	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	<p>Original Prescription Strength</p> <p><b>Cetirizine Hydrochloride Tablets 10 mg</b>          ANTIHISTAMINE</p> <p><b>HIVES RELIEF</b></p> <p>24 Hour Relief of itching due to hives</p> <p>100 TABLETS</p> <p>DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING</p>  <p>LOT NO.          EXP. <b>CODE AREA</b></p> <p>YARRETTA, PA. 17351</p>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>trouble swallowing</li> <li>dizziness or loss of consciousness</li> <li>swelling of tongue</li> <li>swelling in or around mouth</li> <li>trouble speaking</li> <li>drooling</li> <li>wheezing or problems breathing</li> </ul> <p>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. <b>Not a Substitute for Epinephrine.</b> 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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>to prevent hives from any known cause such as:           <ul style="list-style-type: none"> <li>foods</li> <li>insect stings</li> <li>medicines</li> <li>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.</li> </ul> </li> </ul>
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										

**FORMAT: STANDARD**

**TYPE SIZES:**

**TITLE:** 9 pt Helvetica Bold Cond. Oblique

**TITLE (continued):** 8 pt Helvetica Bold Cond. Oblique (continued) 8 pt Helvetica Cond. Medium

**HEADINGS:** 8 pt Helvetica Bold Cond. Oblique

**SUBHEADINGS:** 6 pt Helvetica Bold Cond.

**TEXT:** 6 pt Helvetica Cond. Medium

**MINIMUM LEADING:** 6.5 pt

**BULLETS:** 5 pt Square with 2 M'S spacing between statements

**HEAVY LINES:** 1.5 pt

**HAIRLINES:** 0.5 pt



FINAL PRINTED LABELING  
 ANDA 78-336  
 CETIRIZINE TABLETS 10 mg (HIVES)  
 7- COUNT BLISTER CARTON

EFB1021  
 FAB3810C1

**Drug Facts (continued)**  
 These statements cover the side effects of antihistamine drugs. The condition can be immediately treated by a health professional. **Immediately.** Symptoms of anaphylaxis **may** occur when hives first appear or **Not a Substitute for Epinephrine.** If your doctor has prescribed an epinephrine injector or "anaphylax" or severe allergic symptoms that could occur with your hives, 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 ■ pollen ■ dust ■ mold ■ pet dander ■ a drug 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. ■ 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 ■ stomach or intestinal problems ■ a condition that could be worsened by antihistamines ■ a condition that could be worsened by antihistamines ■ a condition that could be worsened by antihistamines ■ a condition that could be worsened by antihistamines  
**When using this product:** ■ drowsiness may occur ■ avoid alcoholic drinks ■ avoid alcohol, sedatives, and tranquilizers or sedatives.  
**Ask a doctor or pharmacist before use if you are taking:** ■ other antihistamines ■ other antihistamines ■ other antihistamines  
**When driving a motor vehicle or operating machinery:** ■ avoid alcoholic drinks ■ avoid alcohol, sedatives, and tranquilizers or sedatives.  
**Other information:** ■ store between 20° to 25°C (68° to 77°F)

**Drug Facts (continued)**  
**Stop use and ask a doctor if:** ■ symptoms do not improve after 3 days of treatment ■ symptoms do not improve after 3 days of treatment ■ symptoms do not improve after 3 days of treatment  
**Directions:** ■ one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 3 mg product may be appropriate for less severe symptoms.  
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Drug Facts (continued)**  
**Warnings:** ■ Severe Allergy Warning: Get emergency help immediately if you experience difficulty breathing, swelling of the face, lips, tongue, or throat, or if you have trouble swallowing, wheezing, or loss of consciousness. ■ Swelling of tongue ■ Swelling in or around mouth ■ Trouble swallowing ■ Trouble breathing ■ Trouble breathing ■ Trouble breathing  
**Other information:** ■ Store between 20° to 25°C (68° to 77°F)

DISTRIBUTED BY  
**PERRIGO**  
 ALLEGAN, MI 49010

**Original Prescription Strength**  
**Cetirizine Hydrochloride**  
**Tablets 10 mg**  
 ANTHISTAMINE

**HIVES RELIEF**

24 Hour  
 Relief of itching due to hives

**7 TABLETS**

**CODE AREA**

**Drug Facts (continued)**  
**Inactive ingredients:** cantharidin, FD&C Blue #1, hydroxyethylcellulose, lactose, magnesium stearate, polyethylene glycol, polyethylene glycol, polyethylene glycol, titanium dioxide, triacetin.  
**Questions?** If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.



**FORMAT: MODIFIED**  
**TYPE SIZES:**  
**TITLE:** 8.1 pt Helvetica Bold Cond. Oblique  
**TITLE (continued):** 7 pt Helvetica Bold Cond. Oblique  
**HEADINGS:** 7 pt Helvetica Cond. Medium  
**SUBHEADINGS:** 6 pt Helvetica Bold Cond. Oblique  
**TEXT:** 6 pt Helvetica Medium Cond.  
**LEADING:** minimum 6.2 pt  
**BULLETS:** 5 pt Square with 2 M'S spacing between statements  
**HAIRLINES:** 0.5 pt

35

FINAL PRINTED LABELING  
ANDA 78-336  
CETIRIZINE TABLETS 10 mg  
7-COUNT BLISTER CARD



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