


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-429

LABELING

HDC 010880-7130-7

Cetirizine HCl Capsules 

Antihistamine
Hives Relief

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

20 Liquid-filled capsules **

Active Ingredient Purpose
(in each capsule)
Cetirizine HCl 10 mg Antihistamine

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

Warnings: **Severe Allergic Reaction:** Use emergency medical care if you experience any of the following symptoms:
■ trouble breathing ■ dizziness or loss of consciousness ■ swelling of tongue ■ swelling in or around mouth
■ wheezing or noisy breathing
■ hives or redness or itching
These symptoms may be signs of anaphylactic shock. This condition can be life-threatening if not treated by a health care professional. If you experience any of these symptoms, stop taking this medicine and call your doctor or go to a hospital or up to a few hours later. Hives: Subitaneous EpiPen[®] Hives.

Directions: Adults and children 6 years and over: one 10 mg capsule once daily. Do not take more than one 10 mg capsule in 24 hours. If you experience any of the symptoms listed above, stop taking this medicine and call your doctor. Children under 6 years of age: ask a doctor. Concomitant with liver or kidney disease: ask a doctor.

Manufactured by:
Purdue Pharma, Inc.
4125 Pioneer Blvd.
High Point, NC 27265

Lot # _____
Expiration Date _____

10.125 x 9.0625 Flat
2.125 x 2.125 x 4.5

NDC 010888-7128-12

Cetirizine HCl Capsules, 5 mg

Antihistamine

ALLERGY

Indoor & Outdoor Allergies
24 hour Relief of ■ Sneezing ■ Running Nose
■ Itchy, Watery eyes ■ Itchy Throat or Nose

200 Softgels**
Liquid filled capsules**

NDC 010888-7128-12

Cetirizine HCl Capsules, 5 mg

Antihistamine

ALLERGY

Indoor & Outdoor Allergies
24 hour Relief of ■ Sneezing ■ Running Nose
■ Itchy, Watery eyes ■ Itchy Throat or Nose

200 Softgels**
Liquid filled capsules**

Drug Facts

Active ingredient (in each capsule)

Oxetans 124.5 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 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 any of the following:

- alcohol, beer, wine, and grapefruit juice
- sedatives, tranquilizers, or other drugs
- other antihistamines
- blood thinners
- muscle relaxants
- birth control pills
- other medicines

Stop use and ask a doctor if an allergic reaction to the product occurs. Seek medical help right away.

If pregnant or breast-feeding:

- if breast-feeding, not recommended
- if pregnant, ask a health professional before use

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

Drug Facts (continued)

Directions

adults and children 6 years and over	1 to 2 capsules twice daily depending upon severity of symptoms; do not take more than 2 capsules in 24 hours.
children 6 to 5 years of age	1 capsule twice a day; do not take more than 1 capsule in 24 hours.
children under 6 years of age	ask a doctor.
depression and liver or kidney disease	ask a doctor.

Other information

- Store at 20°-25°C (68°-77°F).
- Avoid light, moisture, and excessive heat above 40°C (104°F).
- Protect from light.
- Do not use if Tamper-Evident seal under bottle cap (marked with "Sealed for Your Protection") is broken or missing.

Inactive ingredients: FD&C Blue #1, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, mannitol, polyvinylpyrrolidone, polyethylene glycol 400, purified water, sodium hydroxide, sodium, stearate.

Questions or comments? call 1-800-447-1148


Manufactured by: **Novartis Pharmaceuticals Corporation**
East Hanover, NJ 07936

Lot: 00000-000000-0

Exp. Date: / /

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NDC 010888-7130-7

Cetirizine HCl Capsules 

Antihistamine
Hives Relief

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

20 Liquid-filled capsules **

Active Ingredient (in each capsule)
Cetirizine HCl 10 mg Antihistamine

Purpose
Uses: relieves itching, redness, hives or an allergic skin reaction from occurring.


Warnings
Severe Allergy: Warning: Get emergency help if you have trouble breathing with any of the following symptoms:
 ■ trouble swallowing ■ dizziness or loss of consciousness ■ swelling of tongue ■ swelling in or around mouth ■ trouble speaking ■ dizziness
 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 include: hives, facial swelling or difficulty breathing.
 Note: Substitute for Epinephrine.

Directions: Adults and children 6 years and over: eat 10 mg capsule one daily. (Over 16s more than one 10 mg capsule at 24 hours. A 5 mg product may be used in children 6 years and over. Ask a doctor. Consults with best or kidney disease: ask a doctor.

Manufactured by:
 Bayer Pharmaceutical Inc.
 4125 Premier Drive
 High Point, NC 27265

Lot # _____
 Expiration Date _____

NDC 010888-7128-7

Cetirizine HCl Capsules 

Antihistamine
Allergy

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

20 Liquid-filled capsules **

Active Ingredient (in each capsule)
Cetirizine HCl 5 mg Antihistamine

Purpose
Uses: temporarily relieves these symptoms: runny nose or itchy nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat

Warnings: Do not use if you have ever had a severe allergic reaction to any of its ingredients or to any antihistamine containing hydroxyzine. Ask a doctor before use if you have liver or kidney problems, or if you are taking other medicines. Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

When using this product: ■ drowsiness may occur. ■ Do not drink alcohol. ■ Do not drive or operate machinery. ■ Do not take a drink if an allergic reaction to the product occurs. ■ Seek medical help right away.

Important Dose-Related Information:
 ■ If you are taking other medicines, ask a health professional before use.

Manufactured by:
 Bayer Pharmaceutical Inc.
 4125 Premier Drive
 High Point, NC 27265


Lot # _____
 Exp. Date _____

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: eat 10 mg capsule one daily. (Over 16s more than one 10 mg capsule at 24 hours. A 5 mg product may be used in children 6 years and over. Ask a doctor. Consults with best or kidney disease: ask a doctor.

Manufactured by:
 Bayer Pharmaceutical Inc.
 4125 Premier Drive
 High Point, NC 27265

Lot # _____
 Exp. Date _____



Drug Facts (continued)

Directions

adults and children 6 years and over	one 10 mg capsule once daily, do not take more than one 10 mg capsule 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 at 20-25°C (68-77°F) ■ avoid high humidity and excessive heat above 40°C (104°F) ■ protect from light
 ■ do not use if Tamper-Evident seal under bottle cap imprinted with "Sealed for Your Protection" is Broken or missing

NDC 010888-7127-7

Cetirizine HCl Capsules, 10 mg


Antihistamine

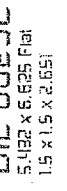
ALLERGY

Indoor & Outdoor Allergies

24 hour Relief of ■ Sneezing ■ Running Nose
 ■ Itchy, Watery eyes ■ Itchy Throat or Nose

20 Softgels**
 Liquid-filled capsules**





Drug Facts

Active ingredient (in each capsule)	Purpose
Cetirizine HCl 10 mg	Antihistamine

Uses

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

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.

DIE 0625C
 15.912 x 5.14 x 5.1
 1.5 x 1.5 x 2.615

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.

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)
Inactive ingredients: FD&C Blue #1, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, mannitol, pharmaceutical ink, polyethylene glycol 400, purified water, sodium hydroxide, sorbitan, sorbitol

Questions or comments?
 call 1-800-441-7140

Expiration Date

Lot #

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Manufactured by:
 Banner Pharmaceuticals, Inc.
 4125 Premier Drive
 High Point, NC 27285

120FS
 PPF

Manufactured by: **Sandoz Pharmaceuticals**
1125 Pennsylvania Ave
Kenilworth, NJ 07033

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Drug Facts (continued)

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 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

Drug Facts (continued)

If pregnant or breast-feeding:

- if breast-feeding, not recommended
- if pregnant, ask a health professional before use.

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

Directions

adults and children 6 years and over	one 10 mg capsule once daily; do not take more than one 10 mg capsule 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 at 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- protect from light
- do not use if Tamper-Evident seal under bottle cap imprinted with "Sealed for Your Protection" is broken or missing

Inactive ingredients: FD&C Blue #1, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, mannitol, pharmaceutical ink, polyethylene glycol-400, purified water, sodium hydroxide, sorbitan, sorbitol.

Questions or comments? call 1-800-441-1140

NDC 010888-7130-12

Cetirizine HCl Capsules, 10 mg
Antihistamine
Hives Relief

24 hour Relief of itching due to hives

200 Softgels™
Liquid filled capsules™

Drug Facts

Active ingredient (in each capsule)	Purpose
Cetirizine HCl 10 mg	Antihistamine

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

Warnings

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

- trouble swallowing
- dizziness or loss of consciousness
- swelling of tongue
- swelling in or around mouth
- trouble speaking
- drooping
- whistling 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.

DIE 0963C
 10.125 x 9.0625 Flat
 2.125 x 2.125 x 4.5

Drug Facts (continued)

If pregnant or breast-feeding:
 ■ If breast-feeding, not recommended ■ If pregnant, ask a health professional before use
Keep out of reach of children. In the 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 capsules daily depending upon severity of symptoms, do not take more than 2 capsules in 24 hours
Children 6 to 5 years and over	1 capsule once a day, do not take more than 2 capsules in 24 hours
Children under 6 years of age	Ask a doctor
Consumers with liver or kidney disease	Ask a doctor

Other Information
 ■ Store at 20-25°C (68-77°F) ■ Avoid high humidity and excessive heat above 40°C (104°F) ■ Protect from light
 ■ Do not use if Terac-Evental seal under bottle cap is damaged with "Check for Your Protection" is broken or missing

Inactive Ingredients FD&C Blue #1, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, mannitol, pharmaceutical ink, polyethylene glycol 400, xanthan gum, sodium hydroxide, croscellan, croscellan

Questions or comments? Call 1-800-447-1140

NDC 010888-7151-12

Cetirizine HCl Capsules, 5 mg
Antihistamine

Hives Relief

24 hour Relief of itching due to hives

200 Softgels**
 Liquid filled capsules**

Drug Facts

Active ingredient (in each capsule)
 Cetirizine HCl 5 mg

Purpose
 Antihistamine

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

Warnings

Serious Allergy Warning: Get emergency help immediately if you have hives along with any of the following symptoms:

- trouble breathing
- dizziness or lightheadedness
- swelling of lips/tongue
- swelling in or around mouth
- trouble speaking
- wheezing or problems breathing
- drooping

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 within minutes first exposure or up to a few hours later. Get a substitute for Epinephrine. If you do not have a substitute, get an epinephrine injector for "anaphylaxis" or another allergic symptoms that could occur with your hives, ensure the capsule is a substitute for an epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Drug Facts (continued)

Do not use

- to prevent hives from any known cause such as: ■ foods ■ insect stings ■ medications ■ latex or rubber gloves

because this product will not cure 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 any other medicine containing hydroxyzine

Ask a doctor before use if you have

- liver or kidney disease. Your doctor should determine if you need a different dose.
- high or low blood pressure, heart disease, or diabetes. ■ May affect blood sugar.
- ask a doctor or pharmacist before use if you are taking tricyclic antidepressants or sedatives.

When using this product

- drowsiness may occur ■ avoid alcohol or 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.

Manufactured by: Spine Pharmaceutical Inc.
 1105 Federal Drive
 High Point, NC 27265

LOT

EXP. DATE



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