

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, film coated
Major Pharmaceuticals

Cetirizine HCL Tablet 10 mg

Drug Facts

Active ingredient (in each tablet)

Cetirizine HCl 10 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

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

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

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

If pregnant or breast-feeding:

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

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

Directions

adults and children 6 years and over	Take 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° and 25°C (68° - 77°F)

Inactive ingredients

Lactose Monohydrate, microcrystalline cellulose, starch (corn), magnesium stearate, hypromellose, polydextrose, polyethylene glycol, and titanium dioxide.

Questions or comments?

call **1-800-706-5575**, weekdays, 8:30am - 5:00pm Eastern Standard Time

Manufactured by:

Apotex Inc.

Toronto, Ontario

Canada M9L 1T9

Manufactured for:

Apotex Corp.

Weston, Florida

33326

Distributed By:

MAJOR® PHARMACEUTICALS

31778 Enterprise Drive

Livonia, MI 48150

Principal Display Panel

Cetirizine 10 mg

Cetirizine Hydrochloride Tablets

Antihistamine/Original Prescription Strength

Indoor & Outdoor Allergies

24 hour

Relief of

- Sneezing
- Runny Nose

- Itchy, Watery Eyes
- Itchy Throat or Nose

Cetirizine HCl Tablets, 10 mg

14 Tablets

Drug Facts

Active ingredient (in each tablet)

Cetirizine HCl, USP 10 mgAntihistamine

Purpose

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

Drug Facts (continued)

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. (1-800-222-1222)

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° and 25°C (68° - 77°F)
■ do not use if carton is opened or if blister unit is torn, broken or shows any signs of tampering
■ meets USP Dissolution Test 3

Drug Facts (continued)

Inactive ingredients

hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, starch (corn) and titanium dioxide

Drug Facts (continued)

Questions or comments? Call 1-800-706-5675

weekdays, 8:30am - 5:00pm Eastern Standard Time

*This product is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc. owner of the registered trademark Zyrtec®

MAJOR®

Original Prescription Strength

NDC 0904-5852-41

*Compare to active ingredient in Zyrtec®

ALL DAY Allergy

Cetirizine HCl Tablets, USP 10 mg

Antihistimine

INDOOR & OUTDOOR ALLERGIES

24 HOUR RELIEF OF:

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose



14 TABLETS
10 mg EACH

MAJOR®

Original Prescription Strength

ALL DAY Allergy

TAMPER EVIDENT: THIS PACKAGE IS SAFETY SEALED & CHILD RESISTANT. DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.

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MAJOR PHARMACEUTICALS
31778 ENTERPRISE DRIVE
LIVONIA, MI 48150, USA
MADE IN CANADA
M-70 08/15

3



5

Principal Display Panel

Cetirizine HCl Tablets, 10 mg

30 Tablets

MAJOR® NDC 0904-5852-46

Original Prescription Strength
ALL DAY Allergy

Cetirizine HCl Tablets, USP 10 mg

Antihistamine
INDOOR & OUTDOOR ALLERGIES

24 HOUR RELIEF OF:
Sneezing
Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose

30 TABLETS
10 mg EACH

388473

Drug Facts
Active ingredient (in each tablet)
Cetirizine HCl, USP 10 mg

Purpose
Antihistamine

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

Warnings
Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.
Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.
When using this product ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery
Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.
If pregnant or breast-feeding: ■ if breast-feeding; not recommended ■ if pregnant; ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

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° and 25°C (68° - 77°F) ■ do not use if seal under bottle cap is broken or missing ■ meets USP Dissolution Test 3

Inactive ingredients carnauba wax, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, starch (corn) and titanium dioxide.

Questions or comments? Call 1-800-706-5575, weekdays, 8:30am - 5:00pm Eastern Standard Time Re-order No. 255548

DISTRIBUTED BY: MAJOR® PHARMACEUTICALS
17177 N LAUREL PARK DRIVE, SUITE 233, LIVONIA, MI 48152, USA
MADE IN CANADA

M-70 Rev. 11/16

Principal Display Panel

Cetirizine HCl Tablets, 10 mg

45 Tablets

MAJOR® NDC 0904-5852-43

Original Prescription Strength
ALL DAY Allergy

Cetirizine HCl Tablets, USP 10 mg

Antihistamine
INDOOR & OUTDOOR ALLERGIES

24 HOUR RELIEF OF:
Sneezing
Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose

45 TABLETS
10 mg EACH

388454

Drug Facts
Active ingredient (in each tablet)
Cetirizine HCl, USP 10 mg

Purpose
Antihistamine

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

Warnings
Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.
Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.
When using this product ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery
Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.
If pregnant or breast-feeding: ■ if breast-feeding; not recommended ■ if pregnant; ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

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° and 25°C (68° - 77°F) ■ do not use if seal under bottle cap is broken or missing ■ meets USP Dissolution Test 3

Inactive ingredients carnauba wax, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, starch (corn) and titanium dioxide.

Questions or comments? Call 1-800-706-5575, weekdays, 8:30am - 5:00pm Eastern Standard Time Re-order No. 255549

DISTRIBUTED BY: MAJOR® PHARMACEUTICALS
17177 N LAUREL PARK DRIVE, SUITE 233, LIVONIA, MI 48152, USA
MADE IN CANADA

M-70 Rev. 11/16

Principal Display Panel

Cetirizine HCl Tablets, 10 mg

90 Tablets

MAJOR® NDC 0904-5852-89

Original Prescription Strength
ALL DAY Allergy

Cetirizine HCl Tablets, USP 10 mg

Antihistamine
INDOOR & OUTDOOR ALLERGIES

24 HOUR RELIEF OF:
Sneezing
Runny Nose
Itchy, Watery Eyes
Itchy Throat or Nose

90 TABLETS
10 mg EACH

388350

Drug Facts
Active ingredient (in each tablet)
Cetirizine HCl, USP 10 mg

Purpose
Antihistamine

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

Warnings
Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.
Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.
When using this product ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery
Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.
If pregnant or breast-feeding: ■ if breast-feeding; not recommended ■ if pregnant; ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

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° and 25°C (68° - 77°F) ■ do not use if seal under bottle cap is broken or missing ■ meets USP Dissolution Test 3

Inactive ingredients carnauba wax, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, starch (corn) and titanium dioxide.

Questions or comments? Call 1-800-706-5575, weekdays, 8:30am - 5:00pm Eastern Standard Time Re-order No. 255550

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17177 N LAUREL PARK DRIVE, SUITE 233, LIVONIA, MI 48152, USA
MADE IN CANADA

M-70 Rev. 11/16

Principal Display Panel

Cetirizine HCl Tablets, 10 mg

100 Tablets

MAJOR® NDC 0904-5852-60
*Compare to active ingredient in Zyrtec®

Original Prescription Strength

ALL DAY Allergy

Cetirizine HCl Tablets, USP 10 mg

Antihistamine
INDOOR & OUTDOOR ALLERGIES

24 HOUR RELIEF OF:
 Sneezing
 Runny Nose
 Itchy, Watery Eyes
 Itchy Throat or Nose



100 TABLETS
 10 mg EACH

TAMPER EVIDENT: THIS PACKAGE IS CHILD RESISTANT. DO NOT USE IF SEAL UNDER BOTTLE CAP IS BROKEN OR MISSING.

Drug Facts

Active ingredient (in each tablet) Cetirizine HCl, USP 10 mg.....Antihistamine	Purpose
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	

DRUG FACTS CONTINUED UNDER LABEL

DISTRIBUTED BY:
MAJOR® PHARMACEUTICALS
 17177 N LAUREL PARK DRIVE, SUITE 233
 LIVONIA, MI 48152, USA
 MADE IN CANADA
 Re-order No.: 255551
 M-70 01/17



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Drug Facts (continued)

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

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

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

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

If pregnant or breast-feeding:

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Drug Facts (continued)

Directions	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° and 25°C (68° - 77°F)
- do not use if seal under bottle cap is broken or missing
- meets USP Dissolution Test 3

Inactive ingredients
 camauaba wax, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, starch (corn) and titanium dioxide.

Questions or comments? Call 1-800-706-5575, weekdays, 8:30am - 5:00pm Eastern Standard Time

*This product is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc. owner of the registered trademark Zyrtec®

Principal Display Panel

Cetirizine HCl Tablets, 10 mg

100 Tablets



NDC 0904-5852-61

Unit Dose
**CETIRIZINE HYDROCHLORIDE
TABLETS**

10 mg.

**ANTI-HISTAMINE
100 TABLETS**



Drug Facts

Active Ingredient (in each tablet)	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.

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. This Unit Dose package is not child resistant and is Intended for Institutional Use Only. In case of overdose, get medical help or contact Poison Control Center right away.

Directions	
adults and children 6 years and over	Take 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
consumer with liver or kidney disease	ask a doctor

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

Inactive ingredients: lactose monohydrate, microcrystalline cellulose, starch (corn), magnesium stearate, hypromellose, polydextrose, polyethylene glycol and titanium dioxide

Questions or comments? (800) 616-2417

M-70

Rev. 09/16

PN:10324-2

Distributed by
MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152 USA
Re-Order No. 301568



NDC 0904-5852-61

Unit Dose

CETIRIZINE HCl 10 mg. TABLETS

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-5852(NDC:60505-2633)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	RECTANGLE (pillow-shaped)	Size	9mm
Flavor		Imprint Code	10MG;APO
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-5852-41	14 in 1 CARTON	12/27/2007	02/29/2020
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0904-5852-43	45 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2007	
3	NDC:0904-5852-46	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2007	
4	NDC:0904-5852-60	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2007	
5	NDC:0904-5852-89	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2007	
6	NDC:0904-5852-61	100 in 1 CARTON	12/27/2007	02/29/2020
6		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078317	12/27/2007	

