

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet**  
**Marlex Pharmaceuticals, Inc**

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**Cetirizine Hydrochloride**

***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**

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**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 sedatives or tranquilizers.

**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, contact a doctor or Poison Control Center (1-800-222-1222) 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° and 25° C (68° and 77° F)
- do not use if imprinted safety seal under cap is broken or missing.

### Inactive ingredients

corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide

Manufactured for/ Distributed by:

Marlex Pharmaceuticals, Inc.

New Castle, DE 19720

Rev. 10/22 SP

### PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label

NDC 10135-0762-30

Allergy Relief  
Cetirizine HCl Tablets, USP 10 mg  
ANTIHISTAMINE

30 TABLETS

NDC 10135-0762-30

**MARLEX**  
PHARMACEUTICALS, INC.

**Cetirizine HCl Tablets, USP**

**10 mg**

**30 TABLETS**

**Drug Facts**

**Active ingredient (in each tablet)** Purpose  
Cetirizine HCl, USP 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** sedatives or tranquilizers.  
**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.  
**If pregnant or breast-feeding** ■ if breast-feeding: not recommended ■ if pregnant: ask a health professional before use.  
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**Directions** ■ **Adults and children 6 years and over:** one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms. ■ **Adults 65 years and over:** Ask a doctor ■ **Children under 6 years of age:** Ask a doctor ■ **Consumers with liver or kidney disease:** Ask a doctor

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**Inactive ingredients** corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide.

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New Castle, DE 19720  
Rev. 10/22 SP

 N 3 10135 76230 9

## PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label

NDC 10135-0762-90

**MARLEX**  
PHARMACEUTICALS, INC.

**Cetirizine HCl Tablets, USP**

**10 mg**

**90 TABLETS**

**Drug Facts**

**Active ingredient (in each tablet)** Purpose  
Cetirizine HCl, USP 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**  
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**Ask a doctor or pharmacist before use if you are taking** sedatives or tranquilizers.  
**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.  
**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, contact a doctor or Poison Control Center (1-800-222-1222) 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° and 25° C (68°F and 77° F) ■ do not use if imprinted safety seal under cap is broken or missing.

**Inactive ingredients** corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide.

Manufactured for /  
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Marlex Pharmaceuticals, Inc.  
New Castle, DE 19720  
Rev. 10/22 SP

 N 3 10135 76290 3

NDC 10135-0762-90

Allergy Relief  
Cetirizine HCl Tablets, USP 10 mg  
ANTIHISTAMINE  
90 TABLETS

## PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label

NDC 10135-0762-01

Allergy Relief  
Cetirizine HCl Tablets, USP 10 mg  
ANTIHISTAMINE  
100 TABLETS

NDC 10135-0762-01

**MARLEX**  
PHARMACEUTICALS, INC.

**Cetirizine HCl Tablets, USP**

**10 mg**

**100 TABLETS**

<b>Drug Facts</b>	<b>Purpose</b> Cetirizine HCl, USP 10 mg ..... Antihistamine
<b>Active ingredient (in each tablet)</b>	
<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
<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 sedatives or tranquilizers.
	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.
	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, contact a doctor or Poison Control Center (1-800-222-1222) right away.
<b>Directions</b>	■ Adults and children 6 years and over: one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms. ■ Adults 65 years and over: Ask a doctor ■ Children under 6 years of age: Ask a doctor ■ Consumers with liver or kidney disease: Ask a doctor
<b>Other information</b>	■ store between 20° and 25° C (68°F and 77° F) ■ do not use if imprinted safety seal under cap is broken or missing.
<b>Inactive ingredients</b>	corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide.
Manufactured for / Distributed by: Marlex Pharmaceuticals, Inc. New Castle, DE 19720 Rev. 10/22 SP	
 N 3 10135 76201 9	

## PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label

NDC 10135-0762-03

Allergy Relief  
Cetirizine HCl Tablets, USP 10 mg  
ANTIHISTAMINE

300 TABLETS

NDC 10135-0762-03

**MARLEX**  
PHARMACEUTICALS, INC.

**Cetirizine HCl Tablets, USP**

**10 mg**

**300 TABLETS**

<b>Drug Facts</b>	<b>Purpose</b> Cetirizine HCl, USP 10 mg ..... Antihistamine
<b>Active ingredient (in each tablet)</b>	
<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
<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 sedatives or tranquilizers.
	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.
	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, contact a doctor or Poison Control Center (1-800-222-1222) right away.
<b>Directions</b>	■ Adults and children 6 years and over: one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms. ■ Adults 65 years and over: Ask a doctor ■ Children under 6 years of age: Ask a doctor ■ Consumers with liver or kidney disease: Ask a doctor
<b>Other information</b>	■ store between 20° and 25° C (68°F and 77° F) ■ do not use if imprinted safety seal under cap is broken or missing.
<b>Inactive ingredients</b>	corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide.
Manufactured for / Distributed by: Marlex Pharmaceuticals, Inc. New Castle, DE 19720 Rev. 10/22 SP	
 N 3 10135 76203 3	

## PRINCIPAL DISPLAY PANEL - 10 mg Tablet Bottle Label

NDC 10135-0762-05

Allergy Relief  
Cetirizine HCl Tablets, USP 10 mg  
ANTIHISTAMINE

500 TABLETS



**Drug Facts**

**Active ingredient (in each tablet)** Purpose  
Cetirizine HCl, USP 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 sedatives or tranquilizers.

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.

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, contact a doctor or Poison Control Center (1-800-222-1222) 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° and 25° C (68°F and 77° F) ■ do not use if imprinted safety seal under cap is broken or missing.

**Inactive ingredients** corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc, titanium dioxide.



## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10135-762
<b>Route of Administration</b>	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
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY35J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE (rounded-off)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	RI52
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10135-762-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	
2	NDC:10135-762-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	
3	NDC:10135-762-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	
4	NDC:10135-762-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	
5	NDC:10135-762-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2022	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077498	10/01/2022	

**Labeler** - Marlex Pharmaceuticals, Inc (782540215)

Revised: 9/2025

Marlex Pharmaceuticals, Inc