

ALLEROFF - cetirizine hydrochloride tablet
Corporacion Infarmasa

Drug Facts

Cetirizine HCL 10 mg.....Antihistamine

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

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

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

If pregnant or breast feeding:

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

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

Uses

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

- Runny Nose
- Itchy, water eyes
- Itching of the nose or throat
- Sneezing

If you have questions of a medical nature, please contact your pharmacist, doctor or health care profesional

Questions or comments? 561 338 5221

Do not use if blister unit is broken or lorn

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

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 strength 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

Microcrystalline Cellulose, Lactose Monohydrate, Crosscarmellose Sodium, Magnesium Stearate

Drug Facts

Active Ingredient Purpose
Cetirizine hydrochloride 10 mg.....Antihistamine

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
• avoid alcoholic drinks.
• drowsiness may occur.
• 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)

Uses
Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
• Itchy, watery eyes
• Itching of the nose or throat
• Sneezing

Questions or comments? 561 338 5221
Florida 33487
Suite 240, Boca Raton,
Intramas S.A.,
621 N.W. 57th St.,
Miami, FL 33147
Global Corporation Inc.
Exclusive Distributor

Directions
Adults and children
One 10 mg tablet once daily.

Other Information
• Do not use if blister unit is broken or torn.
• Store between 20° to 25° C (68° to 77° F).

Inactive Ingredients
Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide.

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

Children 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

Lot #:
Expiration Date:

30 Tablets
10 mg each

alleroff

allergy

30 Tablets
10 mg each

alleroff allergy

30 Tablets
10 mg each

alleroff allergy

**Cetirizine HCl/
Antihistamine /
10 mg tablets**

Relief of:

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

alleroff allergy

ALLEROFF

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16853-1307
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (Cetirizine - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10.0 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	150.0 mg
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	5.0 mg
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	50.0 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	2.0 mg

Product Characteristics

Color	white (white)	Score	score with uneven pieces
Shape	ROUND (Tablet)	Size	8mm
Flavor		Imprint Code	None
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16853-1307-2	00000000000003 in 1 BOX		
1	NDC:16853-1307-1	000000000010 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019835	01/01/2010	

Labeler - Corporacion Infarmasa (934098294)

Establishment

Name	Address	ID/FEI	Business Operations
Corporacion Infarmasa		934098294	manufacture

Revised: 2/2010

Corporacion Infarmasa