**ALLEROFF - cetirizine hydrochloride tablet**
**Corporacion Infarmasa**

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**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 hidroxyzine

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 20ºC to 25ºC ( 68ºF to 77ºF)

| | |
|---|---|
| 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 strenght may be appropiate 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, Crosscaramellose Sodium, Magnesium Stearate


Lot #:
Expiration Date:

24 x 115 x 90

## *Drug Facts*

| Active Ingredient (in each tablet) | Purpose |
|---|---|
| Cetirizine 2HCL 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**

- 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 profesional 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:

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

### Directions

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| 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

- Do not use if blister unit is broken or torn.
- Store between 20º to 25 ºC (68º to 77 ºF)

### Inactive ingredients

Microcrystalline cellulose, modified 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 profesional.

Manufactured by Corporacion Infarmasa S.A. Lima, Peru

Exclusive Distributor Global Corporation Inc. 621 N.W.53rd. St., Suite 240, Boca Raton, Florida 33487

Questions or comments? 561 338 5221

# ALLEROFF

cetirizine hydrochloride tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:16853-1305 |
| **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 |
| **CROSCARMELLOSE 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:16853-1305-2 | 00000000000001 in 1 BOX | | |
| **1** | NDC:16853-1305-1 | 0000000000 10 in 1 BLISTER PACK | | |
| **2** | NDC:16853-1305-3 | 0000000002 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