

LEADER ALL DAY ALLERGY- cetirizine hydrochloride tablet, film coated
Cardinal Health

Cardinal Health All Day Allergy 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. (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 20-25°C (68-77°F)
- do not use if blister unit is broken or torn

Inactive ingredients

corn starch, FD&C blue no. 1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin

Questions or comments?

1-800-719-9260

Principal Display Panel

Original Prescription Strength

All Day Allergy

Cetirizine Hydrochloride Tablets, 10 mg Antihistamine

Indoor & Outdoor Allergies

COMPARE TO ZYRTEC® active ingredient

24 Hour Relief of:

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

100 % Money Back Guarantee

14 TABLETS

Actual Size

LEADERTM

Original Prescription Strength

All Day Allergy

Cetirizine Hydrochloride Tablets, 10 mg
Antihistamine

LEADERTM

NDC 70000-0380-1

Original Prescription Strength

All Day Allergy

Cetirizine Hydrochloride Tablets, 10 mg
Antihistamine

Indoor & Outdoor Allergies

24 Hour Relief of:
Sneezing; Runny Nose;
Itchy, Watery Eyes;
Itchy Throat or Nose

COMPARE TO
ZYRTEC[®]
active ingredient*

100% Money
Back Guarantee

14 TABLETS



Actual Size

50 63 99266 :

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.

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 (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 20-25 °C (68-77 °F)
- do not use if blister unit is broken or torn

Inactive ingredients corn starch, FD&C blue no. 1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, polydextrose, polyethylene glycol, povidone, titanium dioxide, triacetin

Tear along perforation, peel off paper and push product through foil. If difficult to open use scissors.

*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Zyrtec[®].

© 2018 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.

Gluten Free

Drug Facts (continued)
Questions or comments? 1-800-719-9260

CIN 5444054 REV. 8/18



CardinalHealth™
 DISTRIBUTED BY CARDINAL HEALTH
 DUBLIN, OH 43017
 www.che.com 1-800-300-6393
 EssentialCare™ since 1999



LEADER ALL DAY ALLERGY

cetirizine hydrochloride tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0380 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------|
| CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:Y07261ME24) | CETIRIZINE HYDROCHLORIDE | 10 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| POLYDEXTROSE (UNII: VH2XOU12IE) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | WHITE | Score | no score |
| Shape | OVAL | Size | 10 mm |
| Flavor | | Imprint Code | 4H2 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70000-0380-3 | 1 in 1 CARTON | 08/13/2018 | |
| 1 | | 70 in 1 BOTTLE; Type 0: Not a Combination Product | | |

| | | | | |
|---|------------------|--|------------|--|
| 2 | NDC:70000-0380-2 | 1 in 1 CARTON | 08/13/2018 | |
| 2 | | 30 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:70000-0380-4 | 1 in 1 CARTON | 08/13/2018 | |
| 3 | | 90 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 4 | NDC:70000-0380-1 | 14 in 1 CARTON | 08/23/2018 | |
| 4 | | 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 | ANDA078336 | 08/13/2018 | |

Labeler - Cardinal Health (097537435)

Revised: 12/2019

Cardinal Health