

SHOPRITE ALLERGY D 12- cetirizine hcl, pseudoephedrine hcl tablet, extended release
Wakefern Food Corporation

ShopRite Allergy D-12 Drug Facts

Active ingredients (in each extended release tablet)

Cetirizine HCl 5 mg

Pseudoephedrine HCl 120 mg

Purpose

Antihistamine

Nasal Decongestant

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
- nasal congestion
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

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.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- thyroid disease
- diabetes
- glaucoma
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- 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

- do not use more than directed
- 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.
- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by fever

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

- do not break or chew tablet; swallow tablet whole

| | |
|--|--|
| adults and children 12 years and over | take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours. |
| adults 65 years and over | ask a doctor |
| children under 12 years of age | ask a doctor |
| consumers with liver or kidney disease | ask a doctor |

Other information

- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, talc, yellow iron oxide

Questions or comments?

1-800-SHOPRITE

Principal Display Panel

Compare to: Active Ingredients in Zyrtec-D®

ALLERGY & CONGESTION

ORIGINAL PRESCRIPTION STRENGTH

ALLERGY D-12

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride

Extended Release Tablets, 5 mg/120 mg – Antihistamine/Nasal Decongestant

INDOOR & OUTDOOR ALLERGIES

12 Hour Relief of: Sneezing; Runny Nose; Itchy, Watery Eyes; Itchy Throat or Nose; Sinus Pressure; Nasal Congestion

actual size

24 extended release tablets



17562 AB C1

Drug Facts (continued)

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Drug Facts (continued)

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Your complete satisfaction or your money back. We welcome your questions and comments. Call: 1-800-ShopRite or Email: www.shoprite.com

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

DISTRIBUTED BY
WAKEFERN FOOD CORP.
5000 RIVERSIDE DRIVE
KEASBEY, NJ 08832 ©2013

Drug Facts (continued)

Questions or comments? 1-800-SHOPRITE

Made in India

* This product is not manufactured or distributed by McNeil Consumer Healthcare, division of McNeil-PPC, Inc., distributor of Zyrtec-D®.



SHOPRITE ALLERGY D 12

cetirizine hcl, pseudoephedrine hcl tablet, extended release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41190-176 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|----------|
| CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24) | CETIRIZINE HYDROCHLORIDE | 5 mg |
| PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DD19F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 120 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HYDROXYPROPYL CELLULOSE (160000 WAMW) (UNII: RFW2ET671P) | |

| | |
|--|--|
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| TALC (UNII: 7SEV7J4R1U) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |

Product Characteristics

| | | | |
|-----------------|--|---------------------|------------|
| Color | WHITE (one side white one side light yellow) | Score | no score |
| Shape | ROUND | Size | 12mm |
| Flavor | | Imprint Code | 5029;5;120 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:41190-176-62 | 4 in 1 CARTON | 09/17/2013 | |
| 1 | | 6 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 | ANDA077170 | 09/17/2013 | |

Labeler - Wakefern Food Corporation (069722418)

Revised: 12/2019

Wakefern Food Corporation