

**CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE-**  
**cetirizine hcl, pseudoephedrine hcl tablet, extended release**  
**Proficient Rx LP**

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**Perrigo Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride 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?**

1-800-719-9260

## Principal Display Panel

Compare to Zyrtec-D® active ingredients

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride

Extended Release Tablets

5 mg/120 mg

Antihistamine / Nasal Decongestant

12 Hour Relief of:

Sneezing

Itchy, Watery Eyes

Runny Nose

Itchy Throat or Nose

Sinus Pressure

Nasal Congestion

actual size

Original Prescription Strength

Indoor & Outdoor Allergies

12 Extended Release Tablets

Allergy & Congestion

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320



NDC 63187-955-24

Lot #:00000

Exp. 00/00/00

SN# MASTER

### Cetirizine HCl 5mg / Pseudoephedrine HCl 120mg

**#24 Tablets**

Each ER tablet contains: Cetirizine HCl 5 mg  
Antihistamine / Pseudoephedrine HCl 120 mg Nasal  
Decongestant

*Round, unscored tablet, with one side light yellow with imprint code " Logo  
and 5029", and other side white with imprint code " 5 / 120"*

Product ID: RC095524

Dist. By: Perrigo Allegan, MI 49010

Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Cetirizine HCl 5mg / Pseudoephedrine HCl 120mg

#24 Tablets

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Cetirizine HCl 5mg / Pseudoephedrine HCl 120mg

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Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320

# CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

cetirizine hcl, pseudoephedrine hcl tablet, extended release

## Product Information

|                                |                |                           |                              |
|--------------------------------|----------------|---------------------------|------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:63187-955(NDC:45802-721) |
| <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      | 5 mg     |
| PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DD19F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 120 mg   |

## Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |          |
| HYDROXYPROPYL CELLULOSE (1600000 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

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

## Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63187-955-24 | 24 in 1 CARTON   | 01/01/2018           |                    |
| 1 |                  | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:63187-955-12 | 12 in 1 CARTON   | 01/01/2018           |                    |
| 2 |                  | 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               | ANDA077170                               | 04/10/2008           |                    |

**Labeler** - Proficient Rx LP (079196022)

**Establishment**

| Name             | Address | ID/FEI    | Business Operations |
|------------------|---------|-----------|---------------------|
| Proficient Rx LP |         | 079196022 | RELABEL(63187-955)  |

Revised: 1/2021

Proficient Rx LP