

**LEVOCETIRIZINE DIHYDROCHLORIDE- levocetirizine dihydrochloride tablet, coated**  
**Rite Aid Corporation**

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**Levocetirizine Dihydrochloride Tablets USP, 5 mg**

**Active ingredient (in each tablet)**

Levocetirizine dihydrochloride USP, 5 mg

**Purpose**

Antihistamine

**Uses**

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

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

**Warnings**

**Do not use**

- if you have kidney disease
- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine

**Ask a doctor before use if you have**

- ever had trouble urinating or emptying your bladder

**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 doctor if**

- you have trouble urinating or emptying your bladder
- 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 65 years of age and older       | <ul style="list-style-type: none"><li>ask a doctor</li></ul>   |
| adults and children 12-64 years of age | <ul style="list-style-type: none"><li>take 1 tablet (5 mg) once daily in the evening</li><li>do not take more than 1 tablet (5 mg) in 24 hours</li><li>1/2 tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms</li></ul> |
| children 6-11 years of age             | <ul style="list-style-type: none"><li>take 1/2 tablet (2.5 mg) once daily in the evening</li><li>do not take more than 1/2 tablet (2.5 mg) in 24 hours</li></ul>   |
| children under 6 years of age          | <ul style="list-style-type: none"><li>do not use</li></ul>   |
| consumers with kidney disease          | <ul style="list-style-type: none"><li>do not use</li></ul>   |

## Other information

- store between 20° and 25°C (68° and 77°F)
- (bottles only) safety sealed: do not use if carton was opened or if printed foil inner seal on bottle is torn or missing
- (blister only) safety sealed: do not use if seal is broken or if individual blister unit is open or torn

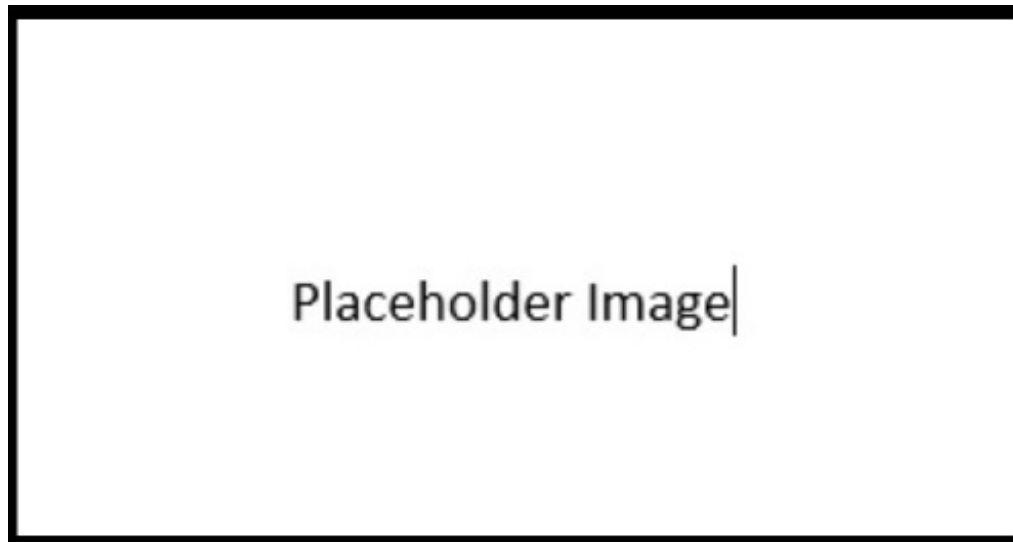
## Inactive ingredients

colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

## Questions or comments?

Call 1-888-375-3784

## PRINCIPAL DISPLAY PANEL- Placeholder image



# LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, coated

## Product Information

|                         |                |                    |                               |
|-------------------------|----------------|--------------------|-------------------------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:11822-5252(NDC:43598-735) |
| Route of Administration | ORAL           |                    |                               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength              | Strength |
|--|--------------------------------|----------|
| levocetirizine dihydrochloride (UNII: SOD6A38AGA) (levocetirizine - UNII:6U5EA9RT2O) | levocetirizine dihydrochloride | 5 mg     |

## Inactive Ingredients

| Ingredient Name                                     | Strength |
|---|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)      |          |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)              |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                  |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)               |          |
| HYPROMELLOSES (UNII: 3NXW29V3WO)                    |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                 |          |
| Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A) |          |

## Product Characteristics

|          |       |              |          |
|----------|-------|--------------|----------|
| Color    | white | Score        | 2 pieces |
| Shape    | OVAL  | Size         | 9mm      |
| Flavor   |       | Imprint Code | L        |
| Contains |       |              |          |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:11822-5252-7 | 1 in 1 CARTON                                      | 02/15/2020           |                    |
| 1 |                  | 35 in 1 BOTTLE; Type 0: Not a Combination Product  |                      |                    |
| 2 | NDC:11822-5252-1 | 1 in 1 CARTON                                      | 02/15/2020           |                    |
| 2 |                  | 120 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA210375                               | 02/15/2020           |                    |

Labeler - Rite Aid Corporation (014578892)

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**Establishment**

| <b>Name</b>                           | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b>                     |
|---------------------------------------|----------------|---------------|--|
| Dr.Reddy's Laboratories Limited-FTO 3 |                | 918608162     | analysis(11822-5252) , manufacture(11822-5252) |

**Establishment**

| <b>Name</b>     | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|-----------------|----------------|---------------|----------------------------|
| Reed-Lane, Inc. |                | 001819879     | repack(11822-5252)         |

Revised: 11/2019

Rite Aid Corporation