

LEVOCETIRIZINE DIHYDROCHLORIDE- levocetirizine dihydrochloride tablet, coated

Rite Aid Corporation

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

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



ORIGINAL
PRESCRIPTION
STRENGTH

allergy relief

levocetirizine dihydrochloride
tablets, 5 mg

antihistamine

24 hour

120 TABLETS
5 mg EACH

Active ingredient (in each tablet)

Levocetirizine dihydrochloride USP, 5 mg.....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 a 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

Purpose

DISTRIBUTED BY: RITE AID
30 HUNTER LANE
CAMP HILL, PA 17011

MADE IN INDIA

LOT / EXP

150072302

Peel Here



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** ■ ask a doctor **adults and children 12-64 years of age** ■ take 1 tablet (5 mg) once daily in the evening ■ do not take more than 1 tablet (5 mg) in 24 hours ■ 1/2 tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms **children 6-11 years of age** ■ take 1/2 tablet (2.5 mg) once daily in the evening ■ do not take more than 1/2 tablet (2.5 mg) in 24 hours **children under 6 years of age** ■ do not use **consumers with kidney disease** ■ do not use **Other information** ■ store between 20° and 25°C (68° and 77°F) ■ safety sealed: do not use if carton was opened or if printed foil inner seal on bottle is torn or missing **Inactive ingredients** colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide **Questions or comments?** call 1-888-375-3784



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: ETJ7Z6XB4) | |
| 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)

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

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