# CHILDRENS LORATADINE- loratadine tablet, chewable TARGET CORPORATION

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#### CHILDREN'S LORATADINE

**Drug Facts** 

### Active ingredient (in each chewable tablet)

Loratadine USP, 5 mg

### **Purpose**

**Antihistamine** 

#### Uses

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

- runny nose
- itchy, watery eyes
- sneezing
- 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.

**Ask a doctor before use if you have**liver or kidney disease. Your doctor should determine if you need a different dose.

When using this product do not take more than directed. Taking more than directed may cause drowsiness.

**Stop use and ask a doctor if**an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding, 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**

chew or crush tablets completely before swallowing.

| adults and       | chew 2 tablets daily; not |
|------------------|---------------------------|
| children 6 years | more than 2 chewable      |

| and over         | tablets in 24 hours      |
|------------------|--------------------------|
| children 2 to    | chew 1 tablet daily; not |
| under 6 years of | more than 1 chewable     |
| age              | tablet in 24 hours       |
| children under 2 | ask a doctor             |
| years of age     |                          |
| consumers with   | ask a doctor             |
| liver or kidney  |                          |
| disease          |                          |

#### Other information

- phenylketonurics: contains phenylalanine 1.25 mg per tablet.
- TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.
- store between 20° to 25°C (68° to 77°F).

### **Inactive ingredients**

aspartame, carmine, citric acid anhydrous, colloidal silicon dioxide, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

### Questions?

Call **1-800-910-6874** 

Distributed by Target Corporation Minneapolis, MN 55403

### PRINCIPAL DISPLAY PANEL - 5 mg Tablet Blister Pack Carton

NDC 11673-310-30

Compare to active ingredient in Children's Claritin ® Chewables\*

Ages 2+ Years

dye-free

children's

allergy

loratadine chewable tablets USP, 5 mg antihistamine

up&up

non-drowsy\*\*
indoor and outdoor allergies
24-hour relief of:

- sneezing
- runny nose

- itchy, watery eyes
- itchy throat or nose

\*\*When taken as directed. See drug facts panel.

30 CHEWABLE TABLETS

THE CHEWABLE TABLETS ARE
TO BE CHEWED BEFORE SWALLOWING

GRAPE FLAVOR

**ACTUAL SIZE** 

30 CHEWABLE TABLETS



# CHILDRENS LORATADINE

loratadine tablet, chewable

| D | roc | duct | Inf | orm   | ation |
|---|-----|------|-----|-------|-------|
| г | 100 | uuct |     | ULILI | auvii |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11673-310

Route of Administration

ORAL

### **Active Ingredient/Active Moiety**

| ı | recive ingredient, recive i loiety                           |                          |          |
|---|--|--------------------------|----------|
|   | Ingredient Name  | <b>Basis of Strength</b> | Strength |
|   | LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN) | LORATADINE               | 5 mg     |

| Inactive Ingredients                                     |          |  |  |
|--|----------|--|--|
| Ingredient Name  | Strength |  |  |
| ASPARTAME (UNII: Z0H242BBR1)                             |          |  |  |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)                 |          |  |  |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                       |          |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)                    |          |  |  |
| MANNITOL (UNII: 30WL53L36A)                              |          |  |  |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)            |          |  |  |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) |          |  |  |
| STEARIC ACID (UNII: 4ELV7Z65AP)                          |          |  |  |

| Product Characteristics |                                 |              |          |
|-------------------------|---------------------------------|--------------|----------|
| Color                   | white (white to off-white)      | Score        | no score |
| Shape                   | ROUND (Flat face, beveled edge) | Size         | 10mm     |
| Flavor                  | GRAPE                           | Imprint Code | LC5      |
| Contains                |                                 |              |          |

| F | Packaging            |   |                         |                       |  |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | tem Code             | Package Description                                     | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:11673-<br>310-30 | 3 in 1 CARTON   | 03/15/2024              |                       |  |
| 1 |                      | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product |                         |                       |  |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| ANDA                  | ANDA210088                                  | 03/15/2024              |                       |
|                       |   |                         |                       |

### Labeler - TARGET CORPORATION (006961700)

# **Registrant -** Ohm Laboratories (051565745)

# **Establishment**

| Name             | Address | ID/FEI    | <b>Business Operations</b> |
|------------------|---------|-----------|----------------------------|
| Ohm Laboratories |         | 184769029 | manufacture(11673-310)     |

Revised: 3/2024 TARGET CORPORATION