

DYE-FREE CHILDRENS LORATADINE- loratadine tablet, chewable
Ohm Laboratories Inc.

Dye-Free Children's Loratadine Chewable Tablets USP, 5 mg

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
- sneezing
- itchy, watery eyes
- 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 children 6 years | chew 2 tablets daily; not more than 2 chewable tablets in |
|-----------------------------|---|

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

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

Questions?

call toll-free Monday to Friday 8:30 am to 5:00 pm EST at **1-800-406-7984**.

Keep the carton. It contains important information. See end panel for expiration date.

Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

0420

PRINCIPAL DISPLAY PANEL - 5 mg Tablet

NDC 51660-112-31

†Compare to the active ingredient of Children's Claritin[®] Chewable

Ages 2+ years

Children's

Loratadine Chewable Tablets USP, 5 mg

Antihistamine

Indoor & Outdoor Allergies

30 CHEWABLE TABLETS

The chewable tablets are to be chewed before swallowing.

Dye-Free

Bubble Gum Flavored

Non-Drowsy*

24 Hour Relief of:

- ***Sneezing***
- ***Runny Nose***
- ***Itchy, Watery Eyes***
- ***Itchy Throat or Nose***

**When taken as directed. See Drug Facts Panel.*

†Ohm® is a registered trademark of Sun Pharmaceutical Industries, Inc. All other trademarks are property of their respective owners.

ohm
Children's
Loratadine Chewable
Tablets USP, 5 mg
BubbleGum
Flavored
Dye-Free
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Drug Facts

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

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Drug Facts (continued)

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| | |
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GLUE - NO COATING

Non Varnish Area

Batch No. _____

Expiration Date: _____

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NDC 51660-112-31

Ages 2+ years

1223

Distributed by:
ohm Laboratories Inc.
New Brunswick, NJ 08801

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5248181

loratadine tablet, chewable

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51660-112 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN) | 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: 3OWL53L36A) | |
| 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 (beveled edge) | Size | 10mm |
| Flavor | BUBBLE GUM | Imprint Code | 112 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:51660-112-31 | 3 in 1 CARTON | 08/19/2020 | |
| 1 | | 10 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 | ANDA210088 | 08/19/2020 | |

Labeler - Ohm Laboratories Inc. (184769029)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|------------------------|
| Ohm Laboratories Inc. | | 184769029 | manufacture(51660-112) |

Revised: 3/2024

Ohm Laboratories Inc.