DYE-FREE CHILDRENS LORATADINE- loratadine tablet, chewable PUBLIX SUPER MARKETS, INC

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

Drug Facts

Active ingredient (in each 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 children 6 years and over | chew 2 tablets daily; not more than 2 tablets in 24 hours | |
|--|---|--|
| | | |
| children 2 to under 6 years | chew 1 tablet daily; not more than | |
| of age | 1 tablet in 24 hours | |
| children under 2 years of | ask a doctor | |
| age | | |
| 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 68° to 77°F (20° to 25°C).

Inactive ingredients

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

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PRINCIPAL DISPLAY PANEL - 5 mg Tablet Blister Pack Carton

NDC 56062-900-20

FOR AGES 2 YEARS AND OLDER INDOOR & OUTDOOR ALLERGIES

children's allergy

LORATADINE CHEWABLE TABLETS USP, 5 mg

ANTIHISTAMINE

Non-drowsy*

24-hour relief of:

- Sneezing Runny nose
- Itchy, watery eyes Itchy throat or nose

DYE FREE

ACTUAL

SIZE

20

CHEWABLE

TABLETS

GRAPE FLAVORED

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

^{*}When taken as directed. See Drug Facts Panel

GLUE - NO COATING

| sak a doctor | consumers with liver or kidney disease |
|--|---|
| sak a doctor | children under 2 years of age |
| chew 1 tablet daily; not more than 1 tablet in 24 hours | children 2 to under 6 years of age |
| chew 2 tablets daily; not more than 2 tablets in 24 hours | adults and children 6 years and over |
| completely before swallowing. | Directions Chew or crush tablets |
| (penunua | nund racts (co |

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Inactive ingredients

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Drug Facts

Loratadine USP, 5 mg Active ingredient (in each tablet) Purpose

 іспу, матегу еуеs ■ runny nose other upper respiratory allergies: temporarily relieves these symptoms due to hay fever or

itching of the nose or throat

(1-800-222-1222):

Ask a doctor before use if you have liver or kidney disease. product or any of its ingredients. Do not use if you have ever had an allergic reaction to this Warnings

Stop use and ask a doctor if an allergic reaction to this Taking more than directed may cause drowsiness. When using this product do not take more than directed.

Your doctor should determine if you need a different dose.

If pregnant or breast-feeding, ask a health professional broduct occurs, Seek medical help right away.

medical help or contact a Poison Control Center right away Keep out of reach of children. In case of overdose, get perore use.

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

*When taken as directed, See Drug Facts Panel

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

GRAPE FLAVORED

ACTUAL

Non Varnish Area

'All trademarks are property of their respective owners. This product is not affiliated the makers/owners of Children's Claritin® Chewables

With

CHEWABLE **TABLETS**

DYE FREE

 Sneezing • Runny nose Itchy, watery eyes
 Itchy throat or nose

24-hour relief of:

Non-drowsy*

ANTIHISTAMINE

LORATADINE CHEWABLE TABLETS USP, 5 mg

children's allergy

FOR AGES 2 YEARS AND OLDER INDOOR & OUTDOOR ALLERGIES NDC 56062-900-20











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ANTIHISTAMINE





DYE-FREE CHILDRENS LORATADINE

loratadine tablet, chewable

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:56062-900 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|----------|--|
| Ingredient Name | Basis of Strength | 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: 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 (bevelled edge) | Size | 10 mm |
| Flavor | GRAPE | Imprint Code | 106 |
| Contains | | | |

| I | Packaging | | | | |
|---|----------------------|---|-----------------------------|---------------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:56062-900- 20 | 2 in 1 CARTON | 09/01/2020 | | |
| 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 | 09/01/2020 | |
| | | | |

Labeler - PUBLIX SUPER MARKETS, INC (006922009)

| Establishment | | | | |
|-----------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Ohm Laboratories Inc. | | 184769029 | MANUFACTURE(56062-900) | |

Revised: 1/2021 PUBLIX SUPER MARKETS, INC