

ALLERGY RELIEF- loratadine tablet
QUALITY CHOICE (Chain Drug Marketing Association)

Drug Facts

Active ingredient (in each tablet)

Loratadine, USP 10 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 (1-800-222-1222) right away.

Directions

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

Other information

- store at 20°-25°C (68°-77°F) (see UPS Controlled Room Temperature)
- protect from light

Inactive ingredients

lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments?

Call **800-935-2362** Monday-Friday 9AM-5PM EST

Principal Display Panel

†Compare to the Active Ingredient in Claritin® 24 Hour

Original Prescription Strength

Allergy Relief

Loratadine 10 mg Tablets

Antihistamine

Indoor & Outdoor Allergies

Relief of:

Sneezing | Runny Nose

Itchy, Watery Eyes | Itchy Throat or Nose

Gluten Free

24 Hour Allergy Relief | Non-Drowsy*

Tablets

*When taken as directed. See Drug Facts panel.

†This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Claritin® 24 Hour

TAMPER EVIDENT: DO NOT USE IF PRINTED SFETY SEAL UNDER CAP IS

BROKEN OR MISSING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Distributed by C.D.M.A., Inc. ©

43157 W 9 Mile Rd

Novi, MI 48375

www.qualitychoice.com

Package Label

| | | | | | | | | |
|--|---|---|-------------------------------|--------------|--|--------------|---|--|
| <p>Drug Facts</p> <p>Active ingredient (in each tablet) Loratadine, USP 10 mg Purpose Antihistamine</p> <p>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</p> <p>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 (1-800-222-1222) right away.</p> <p>Directions</p> <table border="1"> <tr> <td>adults and children 6 years and over</td> <td>1 tablet daily; not more than 1 tablet in 24 hours.</td> </tr> <tr> <td>children under 6 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with liver or kidney disease</td> <td>ask a doctor</td> </tr> </table> <p>Other information ■ store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature) ■ protect from light</p> <p>Inactive ingredients lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate</p> <p>Questions or comments? Call 800-935-2362 Monday-Friday 9AM-5PM EST.</p> <p><small>*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Claritin® 24 Hour.</small></p> <p style="text-align: center; color: red; font-weight: bold;">TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING. KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.</p> | adults and children 6 years and over | 1 tablet daily; not more than 1 tablet in 24 hours. | children under 6 years of age | ask a doctor | consumers with liver or kidney disease | ask a doctor | <p style="text-align: right;">NDC 63868-577-30</p> <p style="text-align: center;">QC QUALITY CHOICE</p> <p style="text-align: center;">*Compare to the Active Ingredient in Claritin® 24 Hour</p> <p style="text-align: center;">Original Prescription Strength</p> <h2 style="text-align: center;">Allergy Relief</h2> <p style="text-align: center;">Loratadine 10 mg Tablets Antihistamine</p> <p style="text-align: center; background-color: #008000; color: white; padding: 2px;">Indoor & Outdoor Allergies</p> <p>Relief of: Sneezing Runny Nose Itchy, Watery Eyes Itchy Throat or Nose Gluten-Free 24 Hour Allergy Relief Non-Drowsy*</p> <p style="text-align: center;">30 Tablets actual size</p> <p style="text-align: center;"><small>*When taken as directed. See Drug Facts panel.</small></p> | <p style="text-align: right;">NDC 63868-577-30</p> <p style="text-align: center;">QC QUALITY CHOICE</p> <p style="text-align: center;">*Compare to the Active Ingredient in Claritin® 24 Hour</p> <p style="text-align: center;">Original Prescription Strength</p> <h2 style="text-align: center;">Allergy Relief</h2> <p style="text-align: center;">Loratadine 10 mg Tablets Antihistamine</p> <p style="text-align: center; background-color: #008000; color: white; padding: 2px;">Indoor & Outdoor Allergies</p> <p>Relief of: Sneezing Runny Nose Itchy, Watery Eyes Itchy Throat or Nose Gluten-Free 24 Hour Allergy Relief Non-Drowsy*</p> <p style="text-align: center;">30 Tablets actual size</p> <p style="text-align: center;"><small>*When taken as directed. See Drug Facts panel.</small></p> |
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| | <p style="text-align: right;">Distributed by C.D.M.A., Inc. © 43157 W 9 Mile Rd Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2362</p> <p style="text-align: center;">6 35515 99735 6</p> <p style="text-align: center; font-weight: bold; font-size: 1.2em;">1 BOTTLE INSIDE</p> <p>PLD-B604A FC006565</p> <p>Lot No: Exp. Date:</p> | | | | | | | |

QUALITY CHOICE Allergy Relief

| | | | |
|--|--------------------------|---------------------------|---------------|
| ALLERGY RELIEF | | | |
| loratadine tablet | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-577 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |

| | | |
|---|------------|-------|
| LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN) | LORATADINE | 10 mg |
|---|------------|-------|

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 6mm |
| Flavor | | Imprint Code | 439 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63868-577-10 | 10 in 1 CARTON | 12/27/2019 | |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:63868-577-30 | 1 in 1 BOX | 12/27/2019 | |
| 2 | | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |
| 3 | NDC:63868-577-01 | 1 in 1 BOX | 12/27/2019 | |
| 3 | | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA075209 | 12/27/2019 | |

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)