

PICNIC ANTIHISTAMINE- loratadine tablet
30M One, Inc.

Thirty Madison Inc Antihistamine Drug Facts

Active ingredient (in each tablet)

Loratadine 10 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

| | |
|--|--|
| 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

- do not use if printed foil under cap is broken or missing
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

Questions or comments?

1-800-719-9260

Principal Display Panel

LORATADINE TABLETS 10 mg

Antihistamine

Compare to the active ingredient in Claritin®

Original Prescription Strength / Non-Drowsy when taken as directed, see Drug Facts Panel

Indoor & Outdoor Allergies / 24 Hour Relief of: Sneezing; Runny Nose; Itchy, Watery Eyes; Itchy Throat or Nose / 100 Tablets for 100 Days of Relief

Actual Size

100 TABLETS



PICNIC ANTIHISTAMINE

loratadine tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80159-103 |
| 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) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | WHITE | Score | no score |
| Shape | OVAL | Size | 8 mm |
| Flavor | | Imprint Code | L612 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:80159-103-01 | 30 in 1 CARTON | 01/19/2021 | |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:80159-103-03 | 1 in 1 CARTON | 01/19/2021 | |
| 2 | | 100 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 | ANDA076301 | 01/19/2021 | |

Labeler - 30M One, Inc. (117621005)