

LORATADINE- loratadine tablet
Blenheim Pharmacal, Inc.

Loratadine Tablet 10 mg

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
- 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.

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

- safety sealed: do not use if induction seal, with "Lift N Peel" tab, under cap is broken or missing

- store between 2° and 30°C (36° and 86°F)
- protect from excessive moisture

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose

| | |
|------------------|-------------------|
| Manufactured by: | Manufactured for: |
| Apotex Inc. | Apotex Corp. |
| Toronto, Ontario | Weston, Florida |
| Canada M9L 1T9 | 33326 |

Revised: March 2005

Principal Display Panel

Loratadine Tablets, USP 10mg

30 Tablets

NDC 10544-455-30



| | | |
|--|--------------------------|---|
| LORATADINE | | |
| loratadine tablet | | |
| Product Information | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) NDC:10544-455(NDC:60505-0147) |
| 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 |
|--|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |

Product Characteristics

| | | | |
|----------|-------|--------------|------------|
| Color | white | Score | no score |
| Shape | OVAL | Size | 8mm |
| Flavor | | Imprint Code | LOR;10;APO |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10544-455-30 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 02/09/2014 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA076471 | 02/09/2014 | |

Labeler - Blenheim Pharmacal, Inc. (171434587)

Registrant - Blenheim Pharmacal, Inc. (171434587)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---------------------|
| Blenheim Pharmacal, Inc. | | 171434587 | repack(10544-455) |

Revised: 2/2015

Blenheim Pharmacal, Inc.