# LORATADINE ALLERGY RELIEF- loratadine tablet NuCare Pharmaceuticals, Inc.

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**Drug Facts** 

# **ACTIVE INGREDIENT(S)**

Loratadine USP, 10 mg

#### **PURPOSE**

Antihistamine

#### USE(S)

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.

#### **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 and kidney disease | ask a doctor                                       |

#### OTHER INFORMATION

- store between 20 and 25° C (68 and 77° F)
- protect from excessive moisture
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

#### INACTIVE INGREDIENTS

Corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch

#### **QUESTIONS?**

Call 1-800-406-7984

#### PRINCIPAL DISPLAY PANEL



### LORATADINE ALLERGY RELIEF

loratadine tablet

| Product Information     |                |                    |                               |  |
|-------------------------|----------------|--------------------|-------------------------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:68071-3208(NDC:51660-526) |  |
| Route of Administration | ORAL           |                    |                               |  |

| ı | Active Ingredient/Active Moiety                              |                   |          |  |  |  |
|---|--|-------------------|----------|--|--|--|
| l | Ingredient Name  | Basis of Strength | Strength |  |  |  |
| ı | LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN) | LORATADINE        | 10 mg    |  |  |  |

| Inactive Ingredients            |                 |          |
|---------------------------------|-----------------|----------|
|                                 | Ingredient Name | Strength |
| STARCH, CORN (UNII: O8232NY3SJ) |                 |          |

# LACTO SE MONO HYDRATE (UNII: EWQ57Q8I5X) MAGNESIUM STEARATE (UNII: 70097M6I30)

| Product Characteristics |                            |              |          |
|-------------------------|----------------------------|--------------|----------|
| Color                   | white (White to Off White) | Score        | no score |
| Shape                   | ROUND                      | Size         | 6 mm     |
| Flavor                  |                            | Imprint Code | RX526    |
| Contains                |                            |              |          |

| P | Packaging        |   |                             |                           |  |
|---|------------------|---|-----------------------------|---------------------------|--|
| # | Item Code        | Package Description                               | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |  |
| 1 | NDC:68071-3208-1 | 10 in 1 BOTTLE; Type 0: Not a Combination Product | 05/17/2017                  |                           |  |
| 2 | NDC:68071-3208-4 | 14 in 1 BOTTLE; Type 0: Not a Combination Product | 05/17/2017                  |                           |  |
| 3 | NDC:68071-3208-7 | 7 in 1 BOTTLE; Type 0: Not a Combination Product  | 05/17/2017                  |                           |  |
| 4 | NDC:68071-3208-2 | 20 in 1 BOTTLE; Type 0: Not a Combination Product | 05/17/2017                  |                           |  |
| 5 | NDC:68071-3208-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 05/17/2017                  |                           |  |
| 6 | NDC:68071-3208-6 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 05/17/2017                  |                           |  |
| 7 | NDC:68071-3208-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 05/17/2017                  |                           |  |

| Marketing Information |  |                      |                    |
|-----------------------|--|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| ANDA                  | ANDA076134                               | 08/28/2003           |                    |
|                       |  |                      |                    |

# Labeler - NuCare Pharmaceuticals, Inc. (010632300)

| Establishment                |         |           |                     |  |
|------------------------------|---------|-----------|---------------------|--|
| Name                         | Address | ID/FEI    | Business Operations |  |
| NuCare Pharmaceuticals, Inc. |         | 010632300 | repack(68071-3208)  |  |

Revised: 2/2021 NuCare Pharmaceuticals, Inc.