LORATADINE- loratadine tablet
Rising Pharmaceuticals, Inc

Loratadine

Drug Facts

Active Ingredient (in each tablet)

Loratadine, 10 mg USP

Purpose

Antihistamine

Uses

Temporarily relieves these symptoms due to hay fever or other respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use if you ever have 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 pregnanct 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 of age 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

- Tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken.
- Store between 20° - 25°C (68°-77°F)

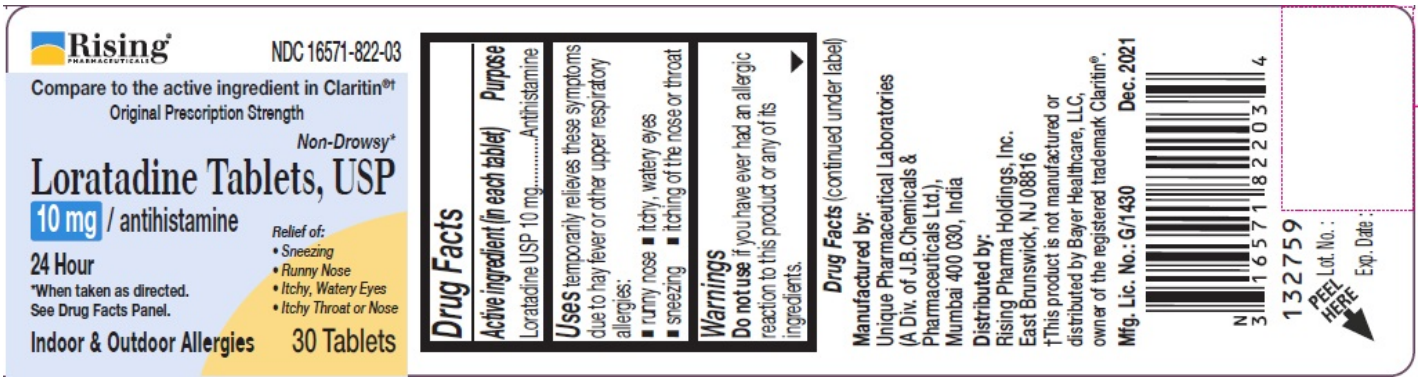
Inactive ingredients corn starch, lactose monohydrate, magnesium stearate, povidone

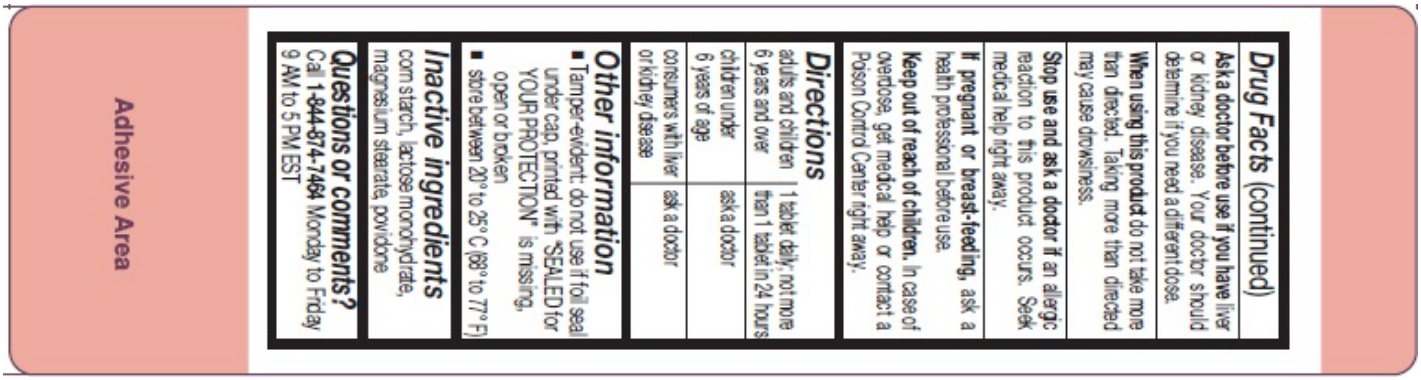
Questions or comments?

Call 1-800-874-7464 Monday to Friday 9 AM to 5 PM EST

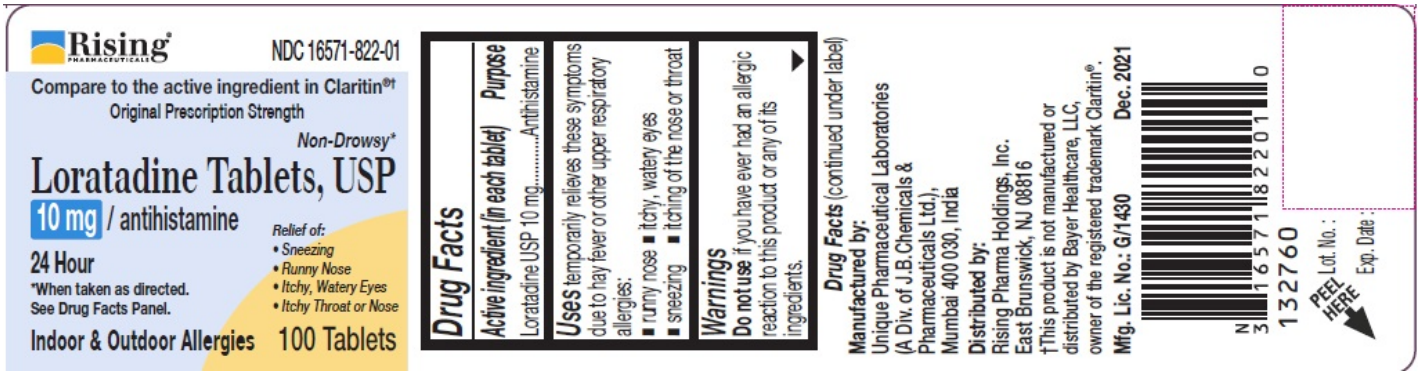
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

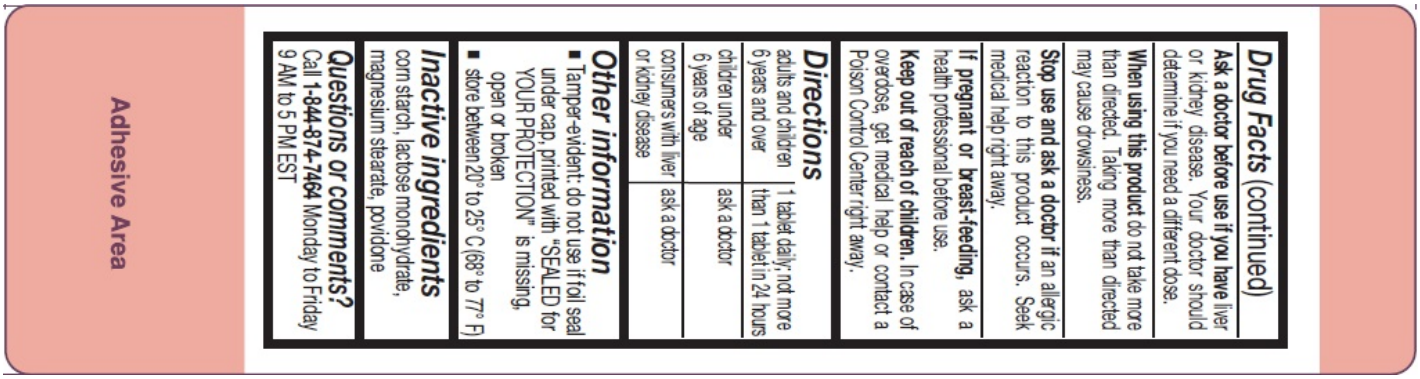
30 Count Container Label





100 Count Container Label





LORATADINE

loratadine tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16571-822
Route of Administration	oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
povidone (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	white (white to off-white)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	10;p
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16571-822-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2022	
2	NDC:16571-822-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2022	
3	NDC:16571-822-30	300 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214684	03/10/2022	

Labeler - Rising Pharmaceuticals, Inc (835513529)

Registrant - Unique Pharmaceuticals Laboratories (650434645)

Establishment

Name	Address	ID/FEI	Business Operations
Unique Pharmaceuticals Laboratories		650434645	manufacture(16571-822)

Revised: 3/2022 Rising Pharmaceuticals, Inc