

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-734

LABELING



Peach Flavor

Loratadine

Oral Suspension 5 mg/5 mL

Antihistamine

UP TO 48 DAYS
OF RELIEF

Children's

Children's Loratadine

Oral Suspension 5 mg/5 mL Antihistamine

NON-DROWSY
ALLERGY

Drug Facts

Active ingredient (in each 5 mL teaspoonful)	Purpose
Loratadine 5 mg	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 you are 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.

Drug Facts (continued)

Directions

Attention: use this product only with the enclosed teaspoon and do not overfill. The enclosed teaspoon holds 5 mL when filled level to top rim. Level by mildly shaking or tapping the spoon.

adults and children 6 years and over	2 teaspoonfuls daily; do not take more than 2 teaspoonfuls daily
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children 2 to under 6 years of age	1 teaspoonful daily; do not take more than 1 teaspoonful daily
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children under 2 years of age	ask a doctor
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consumers with liver or kidney disease	ask a doctor
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Other information

- keep carton for complete information
- do not use if safety seal is torn or missing
- store between 20°-25°C (68°-77°F)
- see bottom of carton or bottle for lot no. and exp. date

Inactive ingredients

butylparaben, carbomer 934p, glycerin, masking agent, peach flavor, poloxamer 188, propylene glycol, purified water, sodium hydroxide, sorbitol crystalline, sucralose liquid concentrate

Questions or comments?

1-800-345-0032
(Monday through Friday,
8 am to 6 pm EST)
www.elixsure.com

NEW! NonSpil™
Technology

Children's Loratadine

Oral Suspension 5 mg/5 mL Antihistamine

NON-DROWSY
ALLERGY

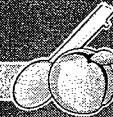
ages two years
and older



Spill Resistant!

- Non-drowsy
- 24-hour relief of
 - sneezing
 - itchy, watery eyes
 - runny nose
 - itchy throat or nose
- Sugar Free

Peach flavor



8 fl oz (240 mL) *When taken as directed, see Drug Facts Panel

Children's
Loratadine
Oral Suspension 5 mg/5 mL
Antihistamine

Unique patented spill-resistant suspension:

- Assures dose goes from spoon to mouth without spilling

Formulated as "NonSpil™ Suspension"

Ingredients Remain Suspended
No need to shake

Attention: Do not overfill the spoon.

- Safety sealed; do not use if safety seal is torn or missing.
- Use this product only with the enclosed measuring device.
- The specially designed teaspoon provided with the product delivers 5 mL when filled to top.
- Level by mildly shaking or tapping the spoon.

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