

**LORATADINE- loratadine solution**  
**Lannett Company, Inc.**

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**Children's Loratadine Oral Solution**

**Loratadine Oral Solution - Allergy**

Active Ingredient: Loratadine 5 mg (in each 5 mL)

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 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***

- use only with enclosed dosing cup
  - mL = milliliter
-

adults and children 6 years and over	10 mL daily; do not take more than 10 mL in 24 hours
children 2 to under 6 years of age	5 mL daily; do not take more than 5 mL in 24 hours
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

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### **Other information**

- **Each 5 mL contains:** sodium 1 mg
- do not use if seal imprinted with "SEALED FOR YOUR PROTECTION" around bottle is not intact
- Store between 20° to 25°C (68° to 77°F)

### **Inactive ingredients**

butylated hydroxyanisole, citric acid, glycerin, grape flavor, propylene glycol, purified water, sodium benzoate, sucralose.

### **Questions or comments?**

1-844-834-0530

Distributed by:  
Lannett Company, Inc.  
Philadelphia, PA 19136

### **Loratadine Oral Solution - Hives Relief**

Active Ingredient: Loratadine 5 mg (in each 5 mL(teaspoonful(tsp)))

Purpose: Antihistamine

### **Uses**

- relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

### **Warnings**

**Severe Allergy Warning:** Get emergency help **immediately** if you have hives along with any of the following symptoms:

- trouble swallowing
- dizziness or loss of consciousness
- swelling of tongue

- swelling in or around mouth
- trouble speaking
- drooling
- wheezing or problems breathing

These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional **immediately**. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

**Not a Substitute for Epinephrine.** If your doctor has prescribed an epinephrine injector for “anaphylaxis” or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

### **Do not use**

- to **prevent** hives from any known cause such as:

- foods
- insects stings
- medicines
- latex or rubber gloves

because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.

- if you have ever had an allergic reaction to this product (loratadine) 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.
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

**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. Get medical help right away**
- symptoms don't improve after 3 days of treatment
- the hives have lasted more than 6 weeks

**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***

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adults and children 6 years and over	2 teaspoonfuls (tsp) daily; do not take more than 2 teaspoonfuls (tsp) in 24 hours
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

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### **Other information**

- Safety sealed. Do not use if imprinted seal around cap is broken or missing
- Store between 20° to 25°C (68° to 77°F)

### ***Inactive ingredients***

Butylated hydroxyanisole, citric acid, glycerin, grape flavor, propylene glycol, purified water, sodium benzoate, sucralose.

### ***Questions***

1-844-834-0530

Manufactured by:  
Silarx Pharmaceuticals, Inc.  
1033 Stoneleigh Ave  
Carmel, NY 10512

### **Patient Leaflet**

**Once Daily / Non-Drowsy\***  
**Loratadine Oral Solution**  
**Hives Relief**  
**5 mg per 5 mL**  
**Antihistamine**

#### **What you should know about:**

**Non- Drowsy\***

**Loratadine Oral Solution - Hives Relief**  
**Original Prescription Strength - 24 Hour Product**

#### **Relief of Itching Due to Hives**

(Please read all of this information before taking Loratadine Oral Solution - Hives Relief Product. Save this leaflet for future reference.)

#### **What is Loratadine Oral Solution - Hives Relief product?**

Loratadine Oral Solution - Hives Relief product contain loratadine, a non-drowsy \*antihistamine.

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**Loratadine Oral Solution - Hives Relief**  
**Original prescription strength medicine to relieve itching due to hives.**

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## **What are hives and what do they look like?**

Hives are itchy raised red or pink bumps, blotches or streaky areas of various sizes on the surface of the skin. They can come and go.

**Do not use this product if your hives look bruised, have an unusual color, or look blistered. These may be signs of a more serious problem. If you have these signs, ask a Doctor before taking Loratadine Oral Solution -Hives Relief product.**

## **What can cause hives?**

Many things, including food, drugs (medicines), insect stings, stress, exercise or temperature can cause hives. A doctor may be able to help you find the cause of your hives. When you know the cause, avoid it.

**Do not use this product to prevent hives or allergic skin reactions known to be caused by food, insect stings, medicines, latex or rubber gloves, or any other causes. Many medicines can cause hives.**

## **How long do hives last?**

Hives can last from a few hours to a few weeks, and often come and go. See a doctor if your hives have lasted more than 6 weeks.

## **Are hives very serious?**

Hives are very common and they are usually not serious. **But in rare cases, they can be the first sign of a life threatening allergic reaction** called anaphylaxis. A sign that you have this serious reaction would be that you have hives along with any of the following symptoms:

- Dizziness or feeling faint
- Trouble swallowing
- Wheezing or problems breathing
- Trouble speaking
- Hives or swelling in or around the mouth
- Drooling

**Hives AND any of these symptoms means call 911 or Get Immediate Medical Help**

**Can I use Loratadine Oral Solution -Hives Relief product instead of an epinephrine injection for my allergic reaction?**

**Never use Loratadine Oral Solution - Hives Relief product as a substitute for epinephrine.**

If your doctor has prescribed an epinephrine injector for your severe allergic reactions, your doctor is concerned that your hives might lead to a severe allergic reaction (anaphylaxis) or to asthma-like symptoms that could occur with your hives. Loratadine Oral Solution - Hives Relief product is not a substitute for epinephrine. If you have been prescribed an epinephrine injector, carry it with you at all times.

## **Who can take Loratadine Oral Solution - Hives Relief Product?**

People who have hives (urticaria) and are 6 years of age or older can take Loratadine

Oral Solution – Hives Relief product. (See label Directions for proper dose.)

### **Who should not take Loratadine Oral Solution – Hives Relief Product?**

- People who have ever had an allergic reaction to these products or any of their ingredients.
- People who are taking any other products containing loratadine
- People with liver or kidney disease unless directed by a doctor
- Children under the age of 6 years.

### **What if I know the cause of my hives and I want to take Loratadine Oral Solution – Hives Relief Product to prevent the hives from occurring?**

Loratadine Oral Solution – Hives Relief product should never be used to prevent hives or allergic skin reactions from any known cause. Such causes can include but are not limited to:

- Food
- Insect Stings
- Medicines
- Latex or rubber gloves.

If you have ever had an allergic reaction to any of these causes, you should see a doctor.

### **When should you contact a doctor?**

**Contact a doctor before taking Loratadine Oral Solution – Hives Relief** product if you have:

- Hives that have an unusual color or that look bruised or blistered
- Hives that have lasted longer than 6 weeks

If you are pregnant or breast feeding, you should ask a doctor or health professional before use.

**Contact a doctor while taking Loratadine Oral Solution – Hives Relief Product** if you (or your child) have:

- A rash or itching that does not get better after taking Loratadine Oral Solution – Hives Relief product for 3 days
- Hives that keep coming back.

### **How long can Loratadine Oral Solution – Hives Relief product be taken to relieve the itching?**

Loratadine Oral Solution – Hives Relief product can be taken during the entire time that you have itching due to hives (see Directions). Don't forget, if the hives last longer than 6 weeks, contact your doctor.

### **How should Loratadine Oral Solution – Hives Relief product be taken?**

- Adults and children 6 years and older should take 2 teaspoonfuls of Loratadine Oral Solution (10 mg) daily.
- Do not take more than one dose in 24 hour period.
- If you have liver or kidney disease, ask a doctor.

### **What else can I do to make the itching and rash feel better?**

Wear loose clothing to help reduce irritation. Keeping the temperature cool can help with the itching.

**Other important information:**

- Allergy Alert: Do not use if you are allergic to loratadine, any of its ingredients, or other antihistamines.
- If you have been prescribed an epinephrine injector, you should carry it with you at all times.
- Keep out of reach of children.
- In case of an overdose, get medical help or contact a Poison Control Center right away.

\* When taken as directed. See drug facts panel on carton.

Silarx Pharmaceuticals, Inc.

1033 Stoneleigh Ave.  
Carmel, NY 10512

10-1108

Rev. 11/17

**5 mg/5 mL**  
**Loratadine**  
**Oral Solution**  
*Children's*

Unvarnished Area for 2D

**Drug Facts**

**Active ingredient**      **Purpose**  
(in each 5 mL)  
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 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**

■ use only with enclosed dosing cup  
 ■ mL = milliliter

adults and children 6 years and over	10 mL daily; do not take more than 10 mL in 24 hours
children 2 to under 6 years of age	5 mL daily; do not take more than 5 mL in 24 hours
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

**Other information**

■ Each 5 mL contains: sodium 1 mg  
 ■ do not use if seal imprinted with "SEALED FOR YOUR PROTECTION" around bottle is not intact  
 ■ Store between 20° to 25°C (68° to 77°F)

**Inactive ingredients**  
butylated hydroxyanisole, citric acid, glycerin, grape flavor, propylene glycol, purified water, sodium benzoate, sucralose.

**Questions or comments?**  
1-844-834-0530



NDC 54838-558-40

**Grape Flavor**  
Ages 2 years and older

**Children's**  
**Loratadine**  
**Oral Solution**

**Allergy**

5 mg/5 mL

**ANTIHISTAMINE**

**Non-Drowsy\***

**24 Hour Relief of**

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

- Indoor and Outdoor Allergies*
- Dye-Free
- Alcohol-Free
- Sugar-Free
- Grape Flavor

\* When taken as directed, See Drug Facts Panel.

120 mL (4 FL OZ)



NDC 54838-558-40

**Grape Flavor**  
Ages 2 years and older

**Children's**  
**Loratadine**  
**Oral Solution**

**Allergy**

5 mg/5 mL

**ANTIHISTAMINE**

**Non-Drowsy\***

**24 Hour Relief of**

- Sneezing
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- Itchy Throat or Nose

- Indoor and Outdoor Allergies*
- Dye-Free
- Alcohol-Free
- Sugar-Free
- Grape Flavor

\* When taken as directed, See Drug Facts Panel.

120 mL (4 FL OZ)

Dosage Cup Enclosed  
**SAVE THIS CARTON FOR FULL LABELING INFORMATION**  
See top flap of the carton for Control No. and Expiration Date.

Distributed by:  
Lannett Company, Inc.  
Philadelphia, PA 19136

CIB721548    Rev. 06/25



N 3      54838-558-40      1

5 mg/5 mL  
**Hives Relief**

**Loratadine**  
Oral Solution

Sunlase Coating

**Drug Facts**

**Active Ingredient**      **Purpose**  
(in each 5 mL (teaspoonful) (tsp))  
Loratadine 5 mg ..... Antihistamine

**Uses**  
 ■ relieves itching due to hives (urticaria).  
 This product will not prevent hives or an allergic skin reaction from occurring.

**Warnings**  
**Severe Allergy Warning:** Get emergency help immediately if you have hives along with any of the following symptoms:  
 ■ trouble swallowing  
 ■ dizziness or loss of consciousness  
 ■ swelling of tongue  
 ■ swelling in or around mouth  
 ■ trouble speaking  
 ■ drooling  
 ■ wheezing or problems breathing  
 These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional immediately. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

**Not a Substitute for Epinephrine.** If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

**Do not use**  
 ■ to prevent hives from any known cause such as:  
 ■ foods                      ■ insects stings  
 ■ medicines                ■ latex or rubber gloves  
 because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.  
 ■ if you have ever had an allergic reaction to this product (loratadine) or any of its ingredients

**Drug Facts** (continued)

**Ask a doctor before use if you have**  
 ■ liver or kidney disease. Your doctor should determine if you need a different dose.  
 ■ hives that are an unusual color, look bruised or blistered  
 ■ hives that do not itch

**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. Get medical help right away  
 ■ symptoms don't improve after 3 days of treatment  
 ■ the hives have lasted more than 6 weeks

**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	2 teaspoonfuls (tsp) daily; do not take more than 2 teaspoonfuls (tsp) 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 imprinted seal around cap is broken or missing  
 ■ Store between 20° to 25°C (68° to 77°F)

**Inactive Ingredients**  
 Butylated hydroxyanisole, citric acid, glycerin, grape flavor, propylene glycol, purified water, sodium benzoate, sucralose.

**Questions** ☎ 1-844-834-0530

**SILARX**  
NDC 54838-554-40

**Loratadine**  
**Oral Solution**

**Hives Relief**

**Relief of Itching**  
**Due to Hives**  
**5 mg/5 mL**

**ANTIHISTAMINE**  
**Non-Drowsy\***  
**24 hour**

- Dye-Free
- Alcohol-Free
- Sugar-Free
- Grape Flavor

\* When taken as directed.  
See Drug Facts Panel.

Dosage Cup Enclosed  
**120 mL (4 FL OZ)**

SAVE THIS CARTON FOR FULL LABELING INFORMATION

Manufactured by:  
Silarx Pharmaceuticals, Inc.  
1033 Stoneleigh Ave.  
Carmel, NY 10512

10-1012 Rev. 09/17

N 3 54838-554-40 3



loratadine solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54838-558
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	5 mg in 5 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE (grape flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54838-558-40	120 mL in 1 CARTON; Type 0: Not a Combination Product	11/24/2010	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA077421	11/24/2010	

## LORATADINE

loratadine solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54838-554	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN)		LORATADINE	5 mg in 5 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
WATER (UNII: 059QF0KO0R)				
<b>Product Characteristics</b>				
<b>Color</b>		<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	GRAPE (grape flavor)	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:54838-554-40	120 mL in 1 CARTON; Type 0: Not a Combination Product	11/24/2010	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA077421	11/24/2010		
<b>Labeler - Lannett Company, Inc. (002277481)</b>				