

LORATADINE- loratadine solution
NuCare Pharmaceuticals, Inc.

Children's Loratadine Oral Solution

Loratadine Oral Solution - Allergy

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

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 it's 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 2 teaspoonfuls (TSP) daily; do not take more than 2 teaspoonfuls (TSP) in 24 hours

children 2 to under 6 years of age	1 teaspoonful (TSP) daily; do not take more than 1 teaspoonful (TSP) in 24 hours
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- **Each teaspoonful contains:** sodium 1 mg
- 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

1-888-974-5279

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

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

adults and children 6 years 2 teaspoonfuls (tsp) daily; do not take more than 2

and over	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.

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1033 Stoneleigh Ave
Carmel, NY 10512 USA

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.

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

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.
 Carmel, NY 10512
 USA

NuCare Pharmaceuticals, Inc.
 NDC: 68071-4451-4
Children's Loratadine 5mg/5mL
4oz Oral Soln.
 See manufacturer's label for full list of ingredients.
 Product #: R1002504
 STORE AT CONTROLLED TEMPERATURE 68-77°F.

Children's Loratadine 5mg/5mL
 Lot: 000000 NDC: 68071-4451-04
 MFR NDC: 54838-558-40 Exp.: 00-00
 Serial# 0000000002

Children's Loratadine 5mg/5mL
 Lot: 000000 NDC: 68071-4451-04
 MFR NDC: 54838-558-40 Exp.: 00-00
 Serial# 0000000002

GTIN 00368071445145
 Serial# 00000000002
 Exp. Date 00-00
 LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured by: Silarx Pharmaceuticals, Inc. Carmel, NY 10512
 Packaged by: NuCare Pharmaceuticals, Inc. Orange, CA 92667

Take _____ teaspoonful(s) every _____ hours _____ times a day.

Rev 01/01/19
WARNING: KEEP OUT OF REACH OF CHILDREN

LORATADINE		
loratadine solution		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:68071-4451(NDC:54838-558)
Route of Administration	ORAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	LORATADINE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
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

Color		Score	
Shape		Size	
Flavor	GRAPE (grape flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-4451-4	120 mL in 1 BOX; Type 0: Not a Combination Product	05/25/2018	

Marketing Information

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

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-4451)

Revised: 6/2024

NuCare Pharmaceuticals,Inc.