

PATIENT INFORMATION LEAFLET

ESLOTIN 2.5 mg/5 ml Syrup

For Oral use

- **Active substance:** Each 1 mL contains 0.5 mg Desloratadine as active substance.
- **Excipients:** Glycerol, Sodium methyl parahydroxybenzoate, Sodium propyl parahydroxybenzoate, Propylene glycol, Citric acid monohydrate, Saccharose, Trisodium citrate dehydrate, Disodium edetate, Orange flavor, Sunset yellow (E110), Purified water.

Read all of this LEAFLET carefully before you start taking this medicine. Because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *If you go to doctor or hospital at the time of using this medicine, please tell your doctor.*
- *Please follow the instructions exactly. Do not use another **high or low doses** out of recommended.*

In this leaflet:

- 1. What ESLOTIN is and what it is used for**
- 2. Before you use ESLOTIN**
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1. What ESLOTIN is and what it is used for

ESLOTIN is packaged as 100 ml in a bottle with cap.

ESLOTIN is an antiallergic medicine that does not make you drowsy. It helps control your allergic reaction and allergy symptoms.

ESLOTIN relieves the symptoms such as sneeze, nasal discharge and itching, itching on the palate and itching on eyes, lachrymation and redness related to allergic rhinitis (for example, hay fever or allergy to house dust mites).

ESLOTIN is also indicated in relieving the symptoms such as itching co-existing with urticaria, exanthema and redness on skin.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

2. Before you use ESLOTIN

Do not use ESLOTIN in the following conditions;

If,

- You are hypersensitive (allergic) to desloratadine, loratadine, or to any of the other ingredients of ESLOTIN, especially colorant sunset yellow E110.

ESLOTIN is indicated in children 6 months through 11 years of age, adolescents (12 years of age and older), and adults including the elderly.

USE SPECIAL CARE with ESLOTIN in the following conditions;

If,

- You have poor kidney function.

If these warnings apply to you or even if any time in the past, please consult your doctor.

Using ESLOTIN with food and drink

ESLOTIN may be taken with or without a food.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

If you are pregnant, do not use ESLOTIN.

If you notice that you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

If you are breastfeeding, do not use ESLOTIN.

Driving and using machines

At the recommended dose, it is not expected that ESLOTIN cause drowsiness or less alert. However, ESLOTIN may cause drowsiness very rarely in some patients. This case can affect your ability to drive and use machine.

Important information about some excipients in the content of ESLOTIN

Sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate are in content of product as excipient. These excipients may cause allergic reactions (probably delayed). This medicinal product contains sodium less than 1 mmol (23 mg) in each dose; in other words ‘it does not contain sodium ‘ basically.

Sugar (saccharose) is included in content of this medicinal product. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

ESLOTIN contains E110 sunset yellow as colorant. It may cause allergic reactions.

Each 5 ml of this medicinal product contains 250 mg glycerol. Since it contains glycerol less than 10 g/dose, it does not require any warning.

Each 5 ml of this medicinal product contains 420 mg propylene glycol. Since it contains propylene glycol less than 200 mg/kg for children and 400 mg/kg for adults, it does not require any warning.

Using with other medicines

There are no known interactions of ESLOTIN with other medicines.

Please inform your doctor or pharmacist if you are using at present or have recently used any other medicines including medicines without a prescription.

3. How to use ESLOTIN?

Instructions for proper use and dose / frequency of administration:

Children 6 through 11 months of age: take 2.0 ml syrup once a day. Use the measuring cup by filling up to 2 ml.

Children 1 through 5 years of age: take 2.5 ml syrup once a day. Use the measuring cup by filling up to 2.5 ml.

Children 6 through 11 years of age: take 5 ml syrup once a day. Use the measuring cup by filling up to 5 ml.

Adults and adolescents (12 years of age and older): take 10 ml of syrup once a day. Use the measuring cup by filling up 10 ml.

Regarding the duration of treatment, your doctor will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take ESLOTIN.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your doctor will recommend you a treatment schedule in accordance that by evaluating the history of your disease.

If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your doctor may recommend you a longer term treatment.

Treatment duration of urticaria may be variable from patient to patient therefore you should follow the instructions of your doctor.

Route and method of administration

Swallow the syrup, and then drink some water. You may take ESLOTIN with or without food.

Different age groups

Use in children

ESLOTIN is used from 6 months of age upward.

Use in elderly:

Efficacy and safety of ESLOTIN in elderly have not been determined yet.

Specific usage conditions:

Use in liver failure

There is no data related to liver failure.

Use in renal impairment

ESLOTIN should be used carefully in severe renal impairment.

Talk your doctor or pharmacist if you have an impression about the effect of ESLOTIN is very strong or very weak.

If you use more ESLOTIN than you should

Use ESLOTIN only as it is prescribed for you. No serious problems are expected with accidental overdose.

If you use more ESLOTIN than you should, talk your doctor or pharmacist.

If you forget to use ESLOTIN

If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule.

Do not take a double dose to make up for a forgotten dose.

Effects to be occur when treatment of ESLOTIN is terminated

Any effect has not been reported.

4. What are possible side effects?

Like all medicines, side effects may occur in the people who are sensitive to substances in the content of ESLOTIN. Side effects in adults are similar to placebo (a type of drug without therapeutic properties). However, common side effects in children less than 2 years of age are diarrhoea, fever and insomnia, side effects in adults are fatigue, dry mouth and headache.

Undesirable cases are listed in below according to system organ class. Frequencies are defined as;
For different organ systems,

Very common ($\geq 1/10$), common ($\geq 1/100$ and $< 1/10$), uncommon ($\geq 1/1,000$ and $< 1/100$), rare ($\geq 1/10,000$ and $< 1/1,000$), very rare ($< 1/10,000$), unknown (it may not be predicted with available data).

Common: Fatigue

Uncommon: Dry mouth, Headache

Very rare: Allergic reactions (difficulty in breathing, wheezing, itching, hives and rash), hallucinations, stroke, restlessness with increased body movement, palpitations, rapid heartbeat,

abnormal liver function tests, liver inflammation, dizziness, physical and mental hyperactivity, stomach pain, nausea (feeling sick), vomiting, diarrhoea, drowsiness, inability to sleep, muscle pain, flatulence.

If you notice any side effect that is not listed in this leaflet, please inform your doctor or pharmacist.

5. How to store ESLOTIN

Keep out of the reach and sight of children and in its package.

Store below 30°C at room temperature.

Use in accordance with the expiry date.

Do not use ESLOTIN after the expiry date on the package.

Do not use *ESLOTIN* unless you notice any defects in the product and / or packaging.

Marketing Authorization Holder

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Manufacturing Site

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