

## **Package leaflet: Information for the user**

### **Yosqiero 0.5 mg/ml Oral Solution** Desloratadine

**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, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet**

1. What Yosqiero is and what it is used for
2. What you need to know before you take Yosqiero
3. How to take Yosqiero
4. Possible side effects
5. How to store Yosqiero
6. Contents of the pack and other information

#### **1. What Yosqiero is and what it is used for**

Yosqiero oral solution is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

Yosqiero oral solution relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites). These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Yosqiero oral solution is also used to relieve the symptoms associated with urticaria (a skin condition caused by an allergy). These symptoms include itching and hives.

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

Yosqiero oral solution is indicated for children 1 through 11 years of age, adolescents (12 years of age and older), and adults, including the elderly.

#### **2. What you need to know before you take Yosqiero**

##### **Do not take Yosqiero**

- if you are allergic (hypersensitive) to desloratadine, loratadine, or to any of the other ingredients of Yosqiero.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Yosqiero:

- if you have poor kidney function.

If this applies to you, or if you are not sure, please check with your doctor before taking Yosqiero.

### **Other medicines and Yosqiero**

There are no known interactions of Yosqiero with other medicines.

### **Yosqiero with food and drink**

Yosqiero may be taken with or without a meal.

### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy and breastfeeding.

If you are pregnant or nursing a baby, taking Yosqiero Oral Solution is not recommended.

### **Driving and using machines**

At the recommended dose, Yosqiero is not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

### **Yosqiero Oral Solution contains sorbitol, liquid non-crystallizing.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. How to take Yosqiero**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

- Children 1 through 5 years of age: take 2.5 ml ( $\frac{1}{2}$  of a 5 ml spoonful) of oral solution once a day.
- Children 6 through 11 years of age: take 5 ml (one 5 ml spoonful) of oral solution once a day.
- Adults and adolescents (12 years of age and older): take 10 ml (two 5 ml spoonfuls) of oral solution once a day.

In case an oral measuring syringe is provided with the bottle of oral solution, you can alternatively use it to take the appropriate amount of oral solution.

Swallow the dose of oral solution, then drink some water. You can take this medicine with or without food.

### **How to measure the dose**

A measuring spoon marked for doses of 2.5 ml and 5 ml or a 5 ml syringe marked at each 0.5 ml is provided with this medicine. To measure the medicine using the syringe:

- Remove the bottle cap and keep it safely
- Put the end of the syringe into the solution

- Pull the plunger to measure the dose you need
- Remove the syringe from the bottle and close the bottle

If you see air bubbles in the oral syringe after drawing up the solution, turn the oral syringe in an upright position with the tip pointing up. The air will move to the top of the oral syringe. Pull the plunger back towards you and then push it back gently into the oral syringe to get rid of the bubbles. Do not worry about a few tiny bubbles.

Ask your doctor or pharmacist if you need advice on how to measure out the medicine.

#### **Giving the medicine using the syringe:**

- Make sure the child is supported in an upright position.
- Put the tip of the syringe carefully into the child's mouth. Point the tip of the syringe towards the inside of the cheek.
- Slowly push down the plunger of the syringe: Do not squirt it out quickly. The medicine will trickle into the child's mouth.
- Allow the child time to swallow the medicine.

Regarding the **duration of treatment**, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Yosqiero oral solution.

- If your **allergic rhinitis is intermittent** (presence of symptoms for less than 4 days per week or for less than 4 weeks), your physician will recommend you a treatment schedule that will depend on the evaluation of 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 physician may recommend you a longer term treatment.
- For **urticaria**, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your physician.

#### **If you take more Yosqiero than you should**

Take Yosqiero Oral Solution only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more Yosqiero Oral Solution than you were told to, contact your doctor or pharmacist.

#### **If you forget to take Yosqiero**

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- In most children and adults, side effects with Yosqiero were about the same as with a dummy solution or tablet.
- However, common side effects in children less than 2 years of age were diarrhoea, fever and insomnia while in adults, fatigue, dry mouth and headache were reported more often than with a dummy tablet.

During the marketing of Yosqiero, following side effects have been reported very rarely (may affect up to 1 in 10,000 people):

- **Severe allergic reactions** (difficulty in breathing, wheezing, itching, hives and swelling) and rash. **Stop taking** the medicine and **seek medical help immediately** if you experience any of these symptoms.
- Palpitations, rapid heartbeat,
- Stomach pain, nausea (feeling sick), vomiting, upset stomach, diarrhoea,
- Dizziness, drowsiness, inability to sleep,
- Muscle pain, hallucinations, seizures, restlessness with increased body movement,
- Liver inflammation and abnormal liver function tests.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## **5. How to store Yosqiero**

Keep this medicine out of the sight and reach of children.

Do not use Yosqiero after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening of the bottles: 2 months.

This medicinal product does not require any special storage conditions.

Storage condition after first opening of the bottles:

This medicinal product does not require any special storage conditions.

Do not use this medicine if you notice any change in the appearance of the oral solution.

The product should be thrown away after being open for 2 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Yosqiero contains**

- The active substance is desloratadine.  
Each ml of oral solution contains 0.5 mg desloratadine.
- The other ingredients of the oral solution are Sorbitol liquid non-crystallizing (E0420), Propylene glycol, Citric acid monohydrate, Sodium citrate, Hypromellose 2910, Sucralose, Disodium edetate, Tutti frutti flavouring, Purified water.

**What Yosqiero looks like and contents of the pack**

Yosqiero is clear, colourless solution, free from foreign matter, supplied in Type III amber glass bottles closed with a polypropylene child resistant (C/R) screw closure having a multi-ply polyethylene-faced liner.

All packages are supplied with a measuring spoon CE 0373 marked for doses of 2.5 ml and 5 ml or an oral measuring syringe CE 0373 of a final volume of 5 ml marked on every 0.5 ml.

Yosqiero 0.5mg/ml Oral Solution is supplied in 100 ml and is packaged in 100 ml bottles.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturers****Marketing Authorisation Holder:**

Rowex Ltd., Bantry, Co. Cork, Ireland.

**Manufacturers:**

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

LEK S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

Specifar S.A., 1, 28 Octovriou str., Ag. Varvara, 12351 Athens, Greece.

Famar Orleans, 5 avenue de Concyr, 45071 Orleans, CEDEX 2, France.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Denmark	Yosqiero
Ireland	Yosqiero 0.5 mg/ml Oral Solution

**This leaflet was last revised in 11/2013**

Internal code  
Article no.