

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

### **Xyzal 5 mg/ml oral drops, solution**

For adults and children aged 2 years and above

Levocetirizine dihydrochloride

**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. See section 4.

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

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

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

Levocetirizine dihydrochloride is the active ingredient of Xyzal. Xyzal is an antiallergic medication.

For the treatment of signs of illness (symptoms) associated with:

- allergic rhinitis (including persistent allergic rhinitis);
- nettle rash (urticaria).

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

##### **Do not take Xyzal**

- if you are allergic to levocetirizine dihydrochloride, to cetirizine, to hydroxyzine or any of the other ingredients of this medicine (listed in section 6).
- if you have a severe kidney disease requiring dialysis.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Xyzal.

If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Xyzal for several days before testing. This medicine may affect your allergy test results.

If you suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of Xyzal may cause seizure aggravation.

##### **Children**

The use of Xyzal is not recommended for infants and children under 2 years of age.

### **Other medicines and Xyzal**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **Xyzal with food, drink and alcohol**

Caution is advised if Xyzal is taken at the same time as alcohol or other agents acting on the brain.

In sensitive patients, the concurrent administration of Xyzal and alcohol or other agents acting on the brain may cause additional reductions in alertness and impairment of performance.

Xyzal can be taken with or without food.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Some patients being treated with Xyzal may experience somnolence / drowsiness, tiredness and exhaustion. Use caution when driving or operating machinery until you know how this medicine affects you. However, special tests have revealed no impairment of mental alertness, the ability to react or the ability to drive in healthy test persons after taking levocetirizine in the recommended dosage.

### **Xyzal contains methyl parahydroxybenzoate and propyl parahydroxybenzoate**

Methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause allergic reactions (possibly delayed), such as headache, stomach upset, and diarrhoea.

## **3. How to take Xyzal**

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

The recommended dose is:

Adults and adolescents from the age of 12 years: 20 drops once daily.

### **Special dosage instructions for specific populations:**

#### *Renal and hepatic impairment*

Patients with impaired kidney function may be given a lower dose according to the severity of their kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor.

Patients who have a severe kidney disease requiring dialysis must not take Xyzal.

Patients who only have impaired liver function should take the usual prescribed dose.

Patients who have both impaired liver and kidney function may be given a lower dose depending on the severity of the kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor.

#### *Elderly patients aged 65 years and above*

No adaptation of the dose is necessary in elderly patients, provided their renal function is normal.

### **Use in children**

Children from the age of 6 to 12 years: 20 drops once daily.

Children from the age of 2 to 6 years: 5 drops twice daily.

The administration of Xyzal to infants and toddlers aged less than 2 years is not recommended.

**How and when should you take Xyzal?**

For oral use only.

Xyzal may be taken with or without food.

The drops should be poured in a spoon or diluted in water, and taken orally.

If dilution is used, it should be considered, especially for administration to children, that the volume of water to which the drops are added, needs to be adapted according to the quantity of water the patient is able to swallow. The diluted solution should be taken immediately.

When counting the drops, the bottle should be held vertically (top down).

In case of lack of flow of drops, if the right amount of drops has not been delivered, turn the bottle over in upright position, then hold it top down again and continue counting the drops.

**How long should you take Xyzal?**

The duration of use depends on the type, duration and course of your complaints and is determined by your physician.

**If you take more Xyzal than you should**

If you take more Xyzal than you should, somnolence can occur in adults. Children may initially show excitation and restlessness followed by somnolence.

If you think you have taken an overdose of Xyzal, please tell your doctor who will then decide what action should be taken.

**If you forget to take Xyzal**

If you forget to take Xyzal, or if you take a dose lower than that prescribed by your doctor, do not take a double dose to make up for a forgotten dose. Take your next dose at your normal time.

**If you stop taking Xyzal**

Stopping treatment should have no negative effects. However, rarely pruritus (intense itching) may occur if you stop taking Xyzal, even if those symptoms were not present before treatment initiation. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

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.

Common: may affect up to 1 in 10 people

Dry mouth, headache, tiredness and somnolence/drowsiness

Uncommon: may affect up to 1 in 100 people

Exhaustion and abdominal pain

Not known: frequency cannot be estimated from the available data

Other side effects such as palpitations, increased heart rate, fits, pins and needles, dizziness, syncope, tremor, dysgeusia (distortion of the sense of taste), sensation of rotation or movement, visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements), painful or difficult urination, inability to completely empty the bladder, oedema, pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), skin eruption, shortness of breath, weight increase, muscular pain, joint pain, aggressive or agitated behaviour, hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, nightmare, hepatitis, abnormal liver function, vomiting, increased appetite, nausea and diarrhoea have also been reported. Pruritus (intense itching) upon discontinuation.

At the first signs of a hypersensitivity reaction, stop taking Xyzal and tell your doctor. Hypersensitivity reaction symptoms may include: swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties (chest tightness or wheezing), hives, sudden fall in blood pressure leading to collapse or shock, which may be fatal.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Xyzal**

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

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Do not use 3 months after first opening.

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 protect the environment.

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

### **What Xyzal contains**

- The active substance is levocetirizine dihydrochloride.  
1 ml (which is equivalent to 20 drops) contains 5 mg levocetirizine dihydrochloride.
- The other ingredients are sodium acetate trihydrate, acetic acid, propylene glycol, methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), glycerol 85%, saccharin sodium and purified water.

### **What Xyzal looks like and contents of the pack**

The oral drops, solution is a clear from colourless to slightly brownish-yellow solution presented in an amber glass bottle fitted with a dropper insert in natural low density polyethylene and closed with a white polypropylene “child-proof” cap.

Pack sizes: 10 ml, 15 ml, and 20 ml.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

UCB (Pharma) Ireland Limited,

United Drug House,

Magna Business Park, Magna Drive,

Citywest Road,

Dublin 24, Ireland

Manufacturer

Aesica Pharmaceutical S.r.l.  
Via Praglia, 15, I-10044  
Pianezza (Torino)  
Italy

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

Belgium: Xyzall  
Denmark: Xyzal  
Finland: Xyzal  
France: Xyzall  
Germany: Xusal  
Greece: Xozal  
Ireland: Xyzal  
Italy: Xyzal  
Luxembourg: Xyzall  
Norway: Xyzal  
Portugal: Xyzal  
Spain: Xazal

**This leaflet was last revised in 07/2022.**