

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Xyzal® 5mg Film-coated Tablets** (levocetirizine dihydrochloride)

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Xyzal is and what it is used for
2. Before you take Xyzal
3. How to take Xyzal
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### **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. BEFORE YOU TAKE XYZAL**

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

if you are **allergic (hypersensitive)** to levocetirizine dihydrochloride or to an antihistamine or any of the other ingredients of Xyzal (see 'What Xyzal contains') if you have **a severe impairment of kidney function** (severe renal failure with creatinine clearance below 10ml/min).

#### **Take special care with Xyzal**

The use of Xyzal is not recommended in children less than 6 years since the film-coated tablets do not allow for dose adaptation.

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.

#### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

#### **Taking Xyzal with food and drink**

Caution is advised if Xyzal is taken at the same time as alcohol.

In sensitive patients, the simultaneous use of cetirizine or levocetirizine and alcohol or other centrally acting agents may have effects on the central nervous system, although the racemate cetirizine has been shown not to increase the effect of alcohol.

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

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor if you are pregnant, trying to get pregnant or breast-feeding.

#### **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.

#### **Important information about some of the ingredients of Xyzal**

These tablets contain lactose, if you have been told by your doctor that you have an intolerance to some sugars you should contact your doctor before taking them.

### **3. HOW TO TAKE XYZAL**

Always take Xyzal exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### **Dosage:**

The usual dose for adults and children aged 6 years and over is one tablet daily.

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

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 severe impairment of kidney function 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.

Xyzal is not recommended for children under 6 years of age.

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

## How and when should you take Xyzal?

The tablets should be swallowed whole with water and may be taken with or without food.

## 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 compensate; just wait for the foreseen time for intake of the next dose, and take a normal dose as prescribed by your doctor.

## If you stop taking Xyzal

Stopping treatment should have no negative effects. Symptoms may return, but they should not be any worse than they were prior to the treatment.

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

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Xyzal 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, 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, aggressive or agitated behaviour, hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, hepatitis, abnormal liver function, vomiting, increased appetite and nausea, have also been reported.

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 side effects

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

Pharmacovigilance, Earlsfort Terrace,  
IRL - Dublin 2;

Tel: +353 1 6764971 Fax: +353 1 6762517

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

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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

## 5. HOW TO STORE XYZAL

### KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

Do not use Xyzal after the expiry date which is stated on the carton and blister label after 'Exp'. The expiry date refers to the last day of that month.

If your tablets become discoloured or show any other signs of deterioration take them to your pharmacist, for safe disposal.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

## 6. FURTHER INFORMATION

### What Xyzal contains

Each film-coated tablet contains 5mg levocetirizine dihydrochloride as the active ingredient.

The other ingredients are microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, hypromellose (E464), titanium dioxide (E171), and macrogol 400.

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

The film-coated tablets are white to off white, oval, with a 'Y' logo on one side.

They are supplied in blister packs of 30 tablets.

**Manufactured by:** UCB Pharma Ltd., 208 Bath Road, Slough, Berkshire, SL1 3WE, UK.

**Procured from within the EU and repackaged by the PPA holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Xyzal® 5mg Film-coated Tablets**

**POM**

**PPA No: 1328/114/1**

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