

Package leaflet: Information for the patient

Xyzal 5 mg film-coated tablets

For adults and children aged 6 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
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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. 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 suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of Xyzal may cause seizure aggravation.

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.

Children

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

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 lactose

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 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 for adults and children aged 6 years and over is one tablet 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

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

How and when should you take Xyzal?

For oral use only.

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

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

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.

This medicinal product does not require any special storage conditions.

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.
Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.
- 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 1, 2, 4, 5, 7, 10, 2 x 10, 10 x 10, 14, 15, 20, 21, 28, 30, 40, 50, 60,

70, 90 and 100 tablets.

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:

Austria: Xyzall

Belgium: Xyzall
Czech Republic: Xyzal
Cyprus: Xyzal
Denmark: Xyzal
Estonia: Xyzal
Finland: Xyzal
France: Xyzall
Hungary: Xyzal 5 mg filmdoubletta
Germany: Xusal
Greece: Xozal
Ireland: Xyzal
Italy: Xyzal
Latvia: Xyzal
Lithuania: Xyzal
Luxembourg: Xyzall
Malta: Xyzal
Netherlands: Xyzal
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