

Package leaflet: Information for the patient

Xyzal® 0.5 mg/ml oral 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
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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 impairment of kidney function (severe renal failure with creatinine clearance below 10 ml/min).

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 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 maltitol liquid, methyl parahydroxybenzoate and propyl parahydroxybenzoate

- This medicine contains maltitol liquid. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking Xyzal.
- 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: 10 ml solution 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 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.

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: 10 ml solution once daily.

Children from the age of 2 to 6 years: 2.5 ml solution 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.

An oral syringe is supplied with the pack. The solution can be taken undiluted or diluted in a glass of water.

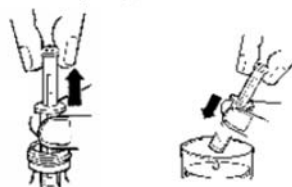
Xyzal may be taken with or without food.

Handling of the oral syringe

Dip the oral syringe into the bottle and draw the plunger up to the mark which corresponds to the dose in millilitres (ml) prescribed by your doctor. For use in children below 6 years of age, the daily dose of 5 ml is measured by removing 2.5 ml of solution from the bottle twice daily (i.e. please cautiously refer to the syringe graduation).

Remove the oral syringe from the bottle and empty its contents into a spoon or into a glass of water by pressing the plunger down. The oral intake of the medicinal product should be performed right after dilution.

Rinse the plunger with water after every use.



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.

gamma-undecalactone, citral, geraniol, citronellol, alpha tocopherol (E307)), purified water

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: 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 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 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 of oral solution contains 0.5 mg levocetirizine dihydrochloride.
- The other ingredients are sodium acetate trihydrate, glacial acetic acid, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), glycerol 85%, maltitol liquid (E965), saccharin sodium, tutti frutti flavouring agent (triacetin (E1518), benzaldehyde, orange oil, vanillin, ethyl butyrate, orange oil concentrated, isoamyl acetate, allyl hexanoate,

What Xyzal looks like and contents of the pack

The oral solution is a clear and colourless solution presented in a glass bottle with a white polypropylene child-resistant closure. The bottle of solution is provided in a cardbox containing also an oral syringe.

Pack size: 200 ml.

Manufacturer

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

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

Xyzal is a registered trademark of UCB Farchim S.A.

Parallel Product Authorisation Number PPA 465/169/2

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

Belgium: Xyzall

Cyprus: Xyzal

Czech Republic: Xyzal

Denmark: Xyzal

Estonia: Xyzal

Finland: Xyzal

France: Xyzall

Germany: Levocetirizin Saft

Greece: Xozal

Hungary: XYZAL 0,5 mg/ml belsóleges oldat

Ireland: Xyzal

Italy: Xyzal

Latvia: Xyzal

Lithuania: Xyzal

Luxembourg: Xyzall

Malta: Xyzal

Netherlands: Xyzal

Norway: Xyzal

Poland: Xyzal

Portugal: Xyzal

Slovak Republic: Xyzal 0,5 mg/ml peroralny roztok

Slovenia: Xyzal

Spain: Xazal

United Kingdom: Xyzal

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