

Xyzal[®] 5 mg 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
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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 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 10 ml/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.

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. If you are intending to drive, engage in potentially hazardous activities or use machines you are therefore advised first to wait and observe your response to the medication. 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.

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.

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.



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

A substantial overdose may cause somnolence 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 the treatment with Xyzal earlier than foreseen should have no detrimental effects, in the sense that the symptoms of the disease should just progressively reappear with a severity not higher than the one experienced prior to treatment with Xyzal.

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. Commonly (1% to 10%), mainly mild to moderate side effects such as dry mouth, headache, tiredness and somnolence/drowsiness have been reported. Uncommon (0.1% to 1%), side effects such as exhaustion and abdominal pain have been observed. Other side effects such as palpitations, increased heart rate, convulsions, visual disturbances, 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, hepatitis, abnormal liver function, nausea and vomiting have also been reported.

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

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.

5. HOW TO STORE XYZAL

Keep out of the reach and sight of children.

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

This medicinal product does not require any special storage conditions.

6. FURTHER INFORMATION

What Xyzal contains

- The active substance is 5 mg 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

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This leaflet was last approved in April 2011