

XYZAL 5 MG FILM-COATED TABLET

Levocetirizine dihydrochloride

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Xyzal carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.
- Always read the label to make sure the product is appropriate for your child's age.

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1. What Xyzal is and what it is used for

The active substance in Xyzal is levocetirizine. Levocetirizine belongs to a group of antiallergic medicines called antihistamines.

Xyzal is used to treat symptoms such as sneezing, a runny nose and watery eyes associated with allergic rhinitis (including persistent allergic rhinitis).

Xyzal is also used to relieve the rashes and itching of chronic urticaria (*hives*).

2. Before you take Xyzal

Don't take Xyzal

- if you are **allergic** (*hypersensitive*) to levocetirizine, cetirizine, hydroxyzine, any piperazine derivatives (closely related active substances of other medicines) or any other ingredients of Xyzal (listed in Section 6)
 - if you have **severe kidney disease** (severe impairment of kidney function with creatinine clearance below 10 ml/min)
 - if you use other antiallergic medicines
- ➔ If you think any of these apply to you, **don't take** Xyzal until you have checked with your doctor.

Take special care with Xyzal

Talk to your doctor or pharmacist before using Xyzal:

- if you have **difficulty passing urine** or you have conditions that make you more likely to be unable to empty your bladder, such as **spinal cord injury** or **enlarged prostate**
 - if you have **kidney problems** (your doctor may lower your dose of Xyzal)
 - if you have **epilepsy** or you are at risk of convulsions (*fits*)
 - if you are pregnant or breast-feeding (see *Pregnancy and breast-feeding* later in Section 2)
- ➔ **Check with your doctor** if you think any of these may apply to you.

Xyzal film-coated tablets are not recommended for children under 6 years, as this formulation does not allow for appropriate dose adaptation.

While you are taking Xyzal

- Avoid alcohol while you are taking Xyzal (see *'Food and drink with Xyzal'* in Section 2).
- Xyzal may affect your allergy test result. If you are scheduled for allergy testing ask your doctor if you should stop taking Xyzal for several days before testing.
- Contact your doctor if you have high temperature (*fever*), shivering or chills, as you may require other type of treatment.

Conditions you need to look out for

Xyzal can make some existing conditions worse, or cause **severe allergic reactions or urinary retention**. Some people may have suicidal thoughts when taking Xyzal. You must look out for certain symptoms while you are taking Xyzal, to reduce the risk of any problems. (see *'Conditions you need to look out for'* in Section 4)

Other medicines and Xyzal

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.

Some medicines may affect how Xyzal works, or make it more likely that you'll have side effects. Xyzal can also affect how some other medicines work. These include:

- **theophylline** (used to treat respiratory diseases such as **asthma**)
- **ritonavir** (used to treat **HIV/AIDS**)
- medicines acting on the brain, for example **other antihistamines** such as hydroxyzine, clemastine, **medicines used to treat anxiety** such as diazepam or **sleeping pills** such as zolpidem (concurrent administration of Xyzal with other agents acting on the brain may cause additional reductions in alertness and impairment of performance. (see 'Food and drink with Xyzal' later in Section 2).

➔ **Tell your doctor or pharmacist** if you are taking any of these.

Food and drink with Xyzal

Caution is advised if you take Xyzal at the same time as alcohol. In sensitive patients, the concurrent administration of Xyzal and alcohol may cause additional reductions in alertness and impairment of performance.

Pregnancy and breast-feeding

There is only limited information about the safety of Xyzal in pregnant women.

Xyzal should therefore be avoided in pregnant women. It can only be administered if necessary and after medical advice.

- **Tell your doctor if you are pregnant** or planning to become pregnant.
- **If you do become pregnant during treatment** with Xyzal, tell your doctor.

The ingredients in Xyzal can pass into breast milk. **If you are breast-feeding, you must check with your doctor** before you take Xyzal.

Driving and using machines

Xyzal at the recommended dose is unlikely to affect your ability to drive or use machines. However, some patients being treated with Xyzal **may feel drowsy, tired or weak** (see 'Possible side effects' in Section 4).

➔ **Don't drive or use machines** unless you are sure you're not affected.

3. How to take Xyzal

How much to take

Always take Xyzal exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Don't take more than the recommended dose.

Don't take Xyzal for longer than **7 days**, without advice of your doctor or pharmacist.

➔ **Contact your doctor** if your symptoms worsen or do not improve after 3 days.

Adults and adolescents 12 years and above

Xyzal 5 mg film-coated tablet

The usual dose of Xyzal is one 5 mg tablet once a day.

Children

Always read the label to make sure the product is appropriate for your child's age.

Children aged 6 to 12 years

Xyzal 5 mg film-coated tablet

The usual dose of Xyzal is one 5 mg tablet, taken once a day.

Patients with kidney and liver disease

If you have kidney problems, you should talk to your doctor or pharmacist before taking Xyzal. Your doctor will decide on the correct dose of Xyzal depending on the illness and the results of blood tests carried out before treatment. Patients who have severe impairment of kidney function must not take Xyzal (see '*Don't take Xyzal*', in section 2).

How to take

Xyzal film-coated tablets

Swallow the tablet whole, with some water.

Take Xyzal once daily, with or without food.

It is best to take Xyzal at bedtime as it can make you feel drowsy.

If you forget to take Xyzal

Don't take an extra dose to make up for a missed dose. Just take your next dose at the usual time.

If you take too much Xyzal

If you take more Xyzal than you should **contact your doctor or pharmacist for advice.** If possible, show them the Xyzal pack.

Symptoms of overdose in adults may include **drowsiness**. Children may initially show **agitation** and **restlessness**, followed by **drowsiness**.

If you stop taking Xyzal

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.

4. Possible side effects

Like all medicines, Xyzal can cause side effects, but not everybody gets them.

Conditions you need to look out for

Severe allergic reactions. These have occurred in a small number of people, but their exact frequency is unknown. Signs include:

- raised and itchy rash (*hives*)
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in swallowing or breathing
- collapse or loss of consciousness

Suicidal thoughts. Some people had suicidal thoughts when taking Xyzal.

Urinary retention. Signs include:

- pain when passing urine or inability to pass urine

→ **Contact a doctor immediately** if you get any of these symptoms. **Stop taking Xyzal.**

Common side effects

These may affect **up to 1 in 10** people:

- headache, feeling drowsy
- dry mouth
- lack of energy
- sleep disorders, diarrhoea, constipation (in children)

Uncommon side effects

These may affect **up to 1 in 100** people:

- stomach pain
- feeling weak
- vomiting, headache (in children)

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown:

- allergic reactions (*hypersensitivity*) including severe allergic reactions (see '*Severe allergic reactions*' earlier in Section 4)
- increased weight, increased appetite
- aggression, agitation, seeing or hearing things that are not really there, depression, difficulty in sleeping, nightmares, suicidal thoughts
- fits (*seizures*), tingling or numbness of the hands or feet, dizziness, fainting, tremor, taste disturbance
- visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements)
- spinning sensation
- fast or irregular heart beats, heart beating faster
- shortness of breath
- feeling sick (*nausea*), vomiting, diarrhoea
- inflammation of the liver
- small patches of swelling and redness of the skin, which may blister
- itching, rash
- itchy, bumpy rash (*hives*) (see '*Severe allergic reactions*' earlier in Section 4)
- muscle and joint pain
- pain when passing urine, inability to pass urine (see '*Urinary retention*' earlier in Section 4)
- swelling caused by fluid

- intense itching (*pruritus*) upon discontinuation.

Other side effects that may show up in blood tests:

- abnormal liver function test (increased amounts of liver enzymes in the blood)

➔ **Talk to your doctor or pharmacist** if you have any of the side effects listed above or if you notice any side effects not listed in this leaflet.

5. How to store Xyzal

Keep out of the sight and reach of children.

Don't take Xyzal after the expiry date shown on the pack.

Don't store Xyzal above 30 °C.

Don't dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

6. Further information

What Xyzal contains

The active substance is levocetirizine dihydrochloride.

Xyzal 5 mg film-coated tablet

Each tablet contains 5 mg levocetirizine dihydrochloride.

The other ingredients are:

Microcrystalline cellulose, Lactose monohydrate, Colloidal anhydrous silica, Magnesium stearate, Hypromellose, Titanium dioxide, Macrogol 400

What Xyzal looks like and contents of the pack

Xyzal film-coated tablets are packed in aluminium blisters placed into cardboard boxes containing 10 and 50 film-coated tablets.

Product Registrant

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