

# XYZAL FILM COATED TABLET

Levocetirizine dihydrochloride (5 mg)

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## What XYZAL is used for

Xyzal is used to treat the symptoms of:

- Allergic rhinitis (inflammation of the mucous membrane inside the nose) including persistent allergic rhinitis
- Chronic idiopathic urticaria (a raised, itchy rash of unknown cause)

## How XYZAL works

Xyzal contains the active ingredient levocetirizine dihydrochloride

Xyzal is an antihistaminic medication. It works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction.

## Before you use XYZAL

### - When you must not use it

Do not take Xyzal

- if you are allergic (hypersensitive) to the active substance, levocetirizine dihydrochloride, cetirizine, hydroxyzine or to an antihistamine, or any of the other ingredients of Xyzal (see section **Product Description**)
- if you have a severe kidney impairment with creatinine clearance below 10 ml/min.

The use of Xyzal is not recommended for infants and children under 6 years.

### *Pregnancy and breastfeeding*

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are pregnant, trying to get

pregnant or breastfeeding. Levocetirizine is excreted in human milk. Talk to your doctor or pharmacist before taking this medicine if you are breastfeeding.

### - Before you start to use it

Tell your doctor if you have any of the following conditions:

- If you have difficulties emptying your bladder due to factors such as spinal cord lesion or prostatic hyperplasia (enlargement of the prostate gland).
- If you have been told by your doctor that you have an intolerance to some sugars. This tablet contains lactose.
- If you have epilepsy or you are at risk of convulsions (fits).

### - Taking other medicines

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

## How to use XYZAL

### - How much to use

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 is:*

- Adults and adolescents 12 years and above: The daily recommended dose is 5mg (1 film-coated tablet).
- Children aged 6 to 12 years: The daily recommended dose is 5mg (1 film-coated tablet).

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

If you have impaired kidney function, you may be given a lower dose according to the severity of your kidney disease, and body weight will be taken into consideration in children. The dose will be determined by your doctor.

If you have end-stage kidney disease or are undergoing dialysis you must not take Xyzal.

No dose adjustment is needed if you have liver impairment alone. However, if you have both liver and kidney impairment, please consult your doctor for dose adjustments.

No dose adjustment is needed in the elderly, provided their kidney function is normal.

### - When to use it

The film-coated tablet must be taken orally, swallowed whole with liquid and may be taken with or without food. It is recommended to take the daily dose in one single intake.

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

### - How long to use it

The duration of use depends on the type, duration and course of your complaints and is determined by your doctor.

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

### - If you forget to use it

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 for a forgotten one. Proceed with administration taking the next dose in time.

### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent attention.

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

- If you stop taking it

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.

**While you are using it**

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Xyzal.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not take any new medicines without consulting your doctor.

Do not give Xyzal to others. It may harm them, even if their symptoms are the same as yours.

- Things to be careful of

Caution is advised if Xyzal is taken at the same time as alcohol. In sensitive people, the simultaneous use of cetirizine or levocetirizine with alcohol or other medicines that act on the brain may affect alertness.

Some people on Xyzal may experience drowsiness, tiredness and lack of energy.

Although clinical trials have revealed no evidence of impairment in mental alertness, special precautions should be considered if you intend to drive or operate machinery.

**Side Effects**

Xyzal may cause potential side effects, such as:

*Common (may affect up to 1 in 100 people to less than 1 in 10 people)*

Dry mouth, headache, tiredness and somnolence/drowsiness

*Uncommon (may affect up to 1 in 1000 people to less than 1 in 100 people)*

Exhaustion and abdominal pain

*Very rare side effects* such as palpitations (irregular heartbeat), increased heart rate, seizures, pins and needles sensation, dizziness, syncope (temporary loss of consciousness), tremor, dysgeusia (distortion of the sense of taste), sensation of spinning, visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements), painful urination, incomplete voiding of bladder, oedema (fluid retention), pruritus (intense itchiness) upon discontinuation, rash, urticaria (swelling, redness and itchiness of skin), skin eruption, shortness of breath, increase in weight and appetite, muscle and joint pain, aggressive or agitated behaviour, hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, nightmares, hepatitis, abnormal liver function, vomiting, nausea and diarrhea have also been reported.

Stop taking Xyzal and consult your doctor immediately as soon as you experience hypersensitivity or any adverse reactions. Hypersensitivity reaction may include: swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties (chest tightness or wheezing) hives, anaphylactic 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting

Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of XYZAL**

- Storage

Keep out of the reach and sight of children.

Do not use Xyzal after the expiry date which is stated on the carton box and blister. The expiry date refers to the last day of that month. Store below 30°C.

Disposal

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 to protect the environment.

**Product Description**

- What it looks like

Tablet: White to off-white, oval, film-coated tablets with a Y logo on one side.

Ingredients

- Active ingredient

Tablet: Film-coated tablet containing 5 mg of levocetirizine dihydrochloride

- Inactive ingredient(s)

Tablet: Microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide, macrogol 400

- MAL number

Xyzal 5mg Film Coated Tablet  
MAL20051323ARZ

**Manufacturer**

Xyzal 5mg Film-Coated Tablets:  
UCB Farchim SA,  
Chemin De Croix-Blanche 10,  
CH-1630 Bulle, Switzerland

**Product Registration Holder**

GlaxoSmithKline Pharmaceutical Sdn Bhd,  
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