

# XYZAL<sup>®</sup> FILM COATED TABLET/ ORAL DROPS

Levocetirizine dihydrochloride (5 mg, 5 mg/ml)

## What is in this leaflet

1. What XYZAL is used for
2. How XYZAL works
3. Before you use XYZAL
4. How to use XYZAL
5. While you are using it
6. Side Effects
7. Storage and Disposal of XYZAL
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## 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 antiallergic 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, or to an antihistamine, or to methyl parahydroxybenzoate, propyl parahydroxybenzoate, 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.

### - 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 or 20 drops).
- Children aged 6 to 12 years: The daily recommended dose is 5mg (1 film-coated tablet or 20 drops).

### *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.

The drops should be poured in a spoon or diluted in water, and taken orally. The diluted solution should be taken immediately. 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.

**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.

When counting the drops, the bottle should be held vertically (top down). In case of lack of flow of drops, if the right amount of drops has not been delivered, turn the bottle over in upright position, then hold it top down again and continue counting the drops.

- *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.

*Oral Drops*

Methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause allergic reactions (possibly delayed),

**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, abdominal pain and headache (oral drops)

*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, painful urination, incomplete voiding of bladder, oedema (fluid retention), pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of skin), skin eruption, shortness of breath, increase in weight and appetite, muscular pain, aggressive or agitated behaviour, hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, hepatitis, abnormal liver function, vomiting, and nausea, 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 calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

**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/label. 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. Oral Drops: Clear and colourless liquid

- *Ingredients*

- Active ingredient

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

Oral Drops: Each 1 ml (equivalent to 20 drops) contains 5 mg levocetirizine dihydrochloride

- Inactive ingredient(s)

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

Oral Drops: Sodium acetate, acetic acid, propylene glycol, glycerol 85%, methyl parahydroxybenzoate, propyl parahydroxybenzoate, saccharin sodium, purified water

- MAL number

Xyzal 5mg Film Coated Tablet  
MAL20051323ARZ

Xyzal Oral Drops 5mg/ml  
MAL10033140AZ

**Manufacturer**

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

Xyzal Oral Drops 5mg/ml:  
Aesica Pharmaceuticals S.r.L,  
ViaPraglia, 15 – 10044 Pianezza, Italy

**Product Registration Holder**

GlaxoSmithKline Pharmaceutical Sdn  
Bhd, Level 6, Quill 9,  
112 Jalan Semangat,  
46300 Petaling Jaya,  
Selangor, Malaysia

**Date of Revision**

28/01/2016

**Serial Number**

BPFK(R4/1)161215/00494