

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

XYZAL

Levocetirizine dihydrochloride 5 mg film-coated tablets

XYZAL tablets contains sugar (63,50 mg lactose monohydrate per tablet)

XYZAL ORAL SOLUTION

Levocetirizine dihydrochloride 0,5 mg/mL oral solution

XYZAL ORAL SOLUTION contains sugar (0,4 g maltitol per mL)

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

XYZAL is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use XYZAL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share XYZAL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You or your child must see a doctor if your symptoms worsen or do not improve after 14 to 21 days.

What is in this leaflet:

1. What XYZAL is and what it is used for
2. What you need to know before you use XYZAL
3. How to take XYZAL
4. Possible side effects
5. How to store XYZAL

6. Contents of the pack and other information.

1. What XYZAL is and what it is used for

The active ingredient, levocetirizine dihydrochloride, is an antihistamine for systemic use. It is used for the treatment of signs of illness (symptoms) associated with:

- allergic rhinitis (including persistent allergic rhinitis)
- chronic nettle rash of unknown origin (chronic idiopathic urticaria).

2. What you need to know before you take XYZAL

Do not take XYZAL:

- if you or your child are hypersensitive (allergic) to levocetirizine dihydrochloride, to cetirizine, to hydroxyzine or any other substances with a similar chemical structure or to one of the other ingredients of XYZAL (listed in section 6 'What XYZAL contains')
- if you or your child have a severe impairment of kidney function.

Warnings and precautions:

Take special care if you have predisposing factors of urinary retention (inability to completely empty your bladder) (e.g. spinal cord lesions, prostatic hyperplasia (enlarged prostate)) as XYZAL may increase the risk of urinary retention.

Tell your doctor if you have a history of epilepsy (seizures/fits/convulsions).

Pruritus (intense itching) and/or urticaria may occur if you stop taking XYZAL.

XYZAL may affect your allergy test results. If you are scheduled for allergy testing, ask your doctor if you should stop taking XYZAL for several days before testing.

Children and adolescents:

XYZAL Oral Solution is not indicated for use in children under 2 years.

The use of XYZAL tablets is not recommended in children under 6 years of age.

Other medicines and XYZAL:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are using:

- 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 medicines acting on the brain may cause additional reductions in alertness and impairment of performance).

XYZAL with food and alcohol:

You may take XYZAL with or without food. XYZAL film-coated tablets should be taken with liquid. Caution is advised if XYZAL is taken at the same time as alcohol. In sensitive patients, the simultaneous use of XYZAL and alcohol or agents affecting the central nervous system may have effects on alertness, impairment of performance and ability to drive and use machines.

Pregnancy and breastfeeding:

It is not recommended to use XYZAL if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking XYZAL.

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 operate machinery you are therefore advised first to wait and observe your response to XYZAL.

XYZAL tablets contain lactose:

If you have been told by your doctor that you have an intolerance to some sugars, you should not take XYZAL tablets.

XYZAL ORAL SOLUTION contains maltitol, methyl parahydroxybenzoate and propyl parahydroxybenzoate:

XYZAL ORAL SOLUTION contains maltitol. If you have been told that you have an intolerance to some sugars, you should not take XYZAL ORAL SOLUTION.

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

3. How to take XYZAL:

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.

The usual dose is:

Adults or children aged 6 years and older:

- XYZAL film-coated tablets: The daily recommended dose is one tablet. The tablets should be swallowed whole with water and may be taken with or without food.
- XYZAL ORAL SOLUTION: The daily recommended dose is 10 mL (2 medicine measurefuls) once daily.

Children from the age of 2 to 6 years:

- XYZAL ORAL SOLUTION: 2,5 mL solution twice daily.

The administration of XYZAL to infants and toddlers aged less than 2 years is not recommended.

If you have the impression that the effect of XYZAL is too strong or too weak, talk to your doctor or pharmacist.

Instruction for use of XYZAL ORAL SOLUTION:

For oral use only.

A dosing syringe is supplied with the pack (see diagram for how to use). The solution can be taken undiluted or diluted in a glass of water.

XYZAL can be taken with or without food.

Handling of the dosing syringe:

Dip the dosing syringe into the bottle and draw the plunger up to the mark which corresponds to the dose in milliliters (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 (please cautiously refer to the syringe graduation).

Remove the dosing pipette 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 medicine should be performed right after dilution.

Rinse the plunger with water after every use.



If you take more XYZAL than you should:

If you take more XYZAL than you should, drowsiness can occur in adults. Children may initially show excitation and restlessness followed by drowsiness.

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to take XYZAL:

Do not take a double dose to make up for forgotten individual doses, just continue taking the amounts stated in the dosage instructions.

Effects when treatment with XYZAL is stopped:

Stopping treatment with XYZAL earlier than foreseen should have no detrimental effects.

4. Possible side effects:

XYZAL can have side effects.

Not all side effects reported for XYZAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking XYZAL, please consult your doctor, pharmacist or health care provider for advice.

If the following happens, stop taking XYZAL and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- swelling of the mouth, tongue, face and/or throat, which may cause breathing or swallowing difficulties
- rash or itching
- sudden fall in blood pressure leading to collapse or shock, which may be fatal.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to XYZAL. You may need urgent medical attention or hospitalisation.

Other side effects include:

Frequent side effects: dry mouth, headache, tiredness and somnolence/drowsiness, diarrhoea and constipation (in children).

Less frequent side effects:

- exhaustion
- abdominal pain
- nausea and vomiting.

Side effects – frequency unknown:

- 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
- irregular heartbeat, seizures, visual disturbances, fainting, tremor, abnormal taste, dizziness
- swelling, pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin)

- shortness of breath, weight increase, appetite increase, muscular pain, aggressive or agitated behavior, insomnia, thoughts of suicide, nightmares
- liver inflammation, abnormal liver function
- small patches of swelling and redness of the skin, which may blister
- itching, rash
- intense itching (pruritus) upon discontinuation.
- joint pain
- painful urination, inability to empty bladder
- swelling caused by fluid.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of XYZAL.

5. How to store XYZAL:

Store all medicines out of reach of children.

Store at or below 30 °C.

Protect XYZAL tablets from moisture.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

6. Contents of the pack and other information

What XYZAL contains:

The active ingredient is called levocetirizine dihydrochloride.

XYZAL film-coated tablets:

Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.

Other ingredients are: colloidal anhydrous silica, hypromellose (E464), macrogol 400, magnesium stearate, microcrystalline cellulose, titanium dioxide (E171), lactose monohydrate.

XYZAL ORAL SOLUTION:

Each 1 mL oral solution contains 0,5 mg levocetirizine dihydrochloride.

Contains as preservatives: 0,675 mg methyl parahydroxybenzoate per mL and 0,075 mg propyl parahydroxybenzoate per mL.

Other ingredients are: acetic acid, glycerol 85 %, purified water, saccharin sodium, sodium acetate, Tutti Frutti flavour (501103A), maltitol.

What XYZAL looks like and contents of the pack:

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

XYZAL film-coated tablets are packaged in blisters (polyamide/aluminium/PVC complex with a push through aluminium lidding foil or polyamide/aluminium/PVC complex with lidding material of paper backed aluminium foil) of 7 or 10 tablets. 1 strip (7 or 10 tablets) or 3 strips (30 tablets) are packed into cardboard boxes.

XYZAL ORAL SOLUTION: Clear and colourless liquid.

XYZAL ORAL SOLUTION is packed in amber glass bottles containing 75 mL or 150 mL of solution and closed by a white polypropylene childproof cap. It is packed in a cardboard box with a graduated syringe for oral dosing.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

Registration numbers:

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XYZAL ORAL SOLUTION: 41/5.7.1/0032

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