

## XYZAL

### SCHEDULING STATUS:

S2

### PROPRIETARY NAME AND DOSAGE FORM:

XYZAL film-coated tablet

XYZAL ORAL SOLUTION

### COMPOSITION:

**Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.**

Contains sugar (63,50 mg lactose monohydrate per tablet).

Other excipients are colloidal anhydrous silica, magnesium stearate, and microcrystalline cellulose.

The tablet is coated with Opadry® Y-1-7000 consisting of hypromellose, titanium dioxide, and macrogol 400.

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

Excipients: 0,675 mg methyl parahydroxybenzoate per ml

0,075 mg propyl parahydroxybenzoate per ml

Contains sugar (0,4 g maltitol per ml).

Other excipients are sodium acetate and acetic acid (for pH adjustment), glycerol 85 %, saccharin sodium, Tutti Frutti flavour (501103A7), and purified water.

### PHARMACOLOGICAL CLASSIFICATION:

A 5.7.1 Antihistaminics

### PHARMACOLOGICAL ACTION:

**Pharmacodynamic properties:**

Levocetirizine, the (R) enantiomer of cetirizine, is a histamine H<sub>1</sub> receptor antagonist.

**Pharmacokinetic properties:**

Levocetirizine is absorbed after oral administration with peak blood levels reached 0,9 hours after oral administration. Plasma levels are linearly related between 2,5 mg and 20 mg.

The extent of metabolism is less than 14 % of the dose.

The plasma half-life is approximately 8 hours in adults. The main route of excretion is via urine, accounting for approximately 85 % of the dose. Approximately 13 % is excreted in the faeces.

Levocetirizine is 90 % bound to human plasma proteins.

**INDICATIONS:**

XYZAL is indicated for the relief of symptoms associated with the following allergic conditions:

- seasonal allergic rhinitis
- perennial allergic rhinitis
- chronic idiopathic urticaria.

**CONTRA-INDICATIONS:**

XYZAL is contra-indicated:

- in hypersensitivity to levocetirizine, to any piperazine derivative or to any of the excipients of XYZAL (see WARNINGS AND SPECIAL PRECAUTIONS)
- in infants and toddlers aged less than two years, as safety and efficacy have not been demonstrated

- during breastfeeding of infants and while pregnant (see PREGNANCY AND LACTATION)
- in patients with end stage renal disease, at less than 10 ml/min creatinine clearance.

## **WARNINGS AND SPECIAL PRECAUTIONS:**

### *Alcohol*

Precaution is recommended with intake of alcohol (see INTERACTIONS). XYZAL lacks significant sedative effects. Patients should, however be warned that a small number of individuals may experience sedation. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants (see INTERACTIONS).

### *Risk of urinary retention*

Caution should be taken in patients with predisposing factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as XYZAL may increase the risk of urinary retention.

### *Infants and children under 2 years*

Data are not sufficient to support the administration of XYZAL to infants and toddlers aged less than 2 years. Therefore administration of XYZAL to infants and toddlers aged less than 2 years is not recommended.

### *Children aged less than 6 years*

The use of the film-coated tablet formulation is not recommended in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation. It is recommended to use XYZAL ORAL SOLUTION.

### *Effects on ability to drive and use machines*

Some patients could experience somnolence, fatigue and asthenia during therapy with XYZAL. Therefore, patients intending to drive, engage in potentially hazardous activities or operate machinery should take their response to XYZAL into account.

### *Excipient warnings*

#### **Tablets**

##### *Lactose*

XYZAL tablets contain lactose/fructose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, the Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take XYZAL tablets. Lactose may have an effect on the glycaemic control of patients with diabetes mellitus.

#### **Oral solution**

##### *Maltitol*

XYZAL ORAL SOLUTION contains maltitol. Patients with the rare hereditary condition of maltitol intolerance should not take XYZAL ORAL SOLUTION.

##### *Methyl parahydroxybenzoate, propyl parahydroxybenzoate*

The presence of methyl parahydroxybenzoate and propyl parahydroxybenzoate may cause allergic reactions (possibly delayed) (see CONTRA-INDICATIONS).

#### **INTERACTIONS:**

No interaction studies have been performed with XYZAL (including no studies with CYP3A4 inducers). Studies with the racemate compound cetirizine demonstrated that there were no clinically relevant adverse interactions (with ketoconazole, erythromycin, azithromycin, cimetidine, pseudoephedrine, glipizide and diazepam).

### *Theophylline*

A decrease in the clearance of cetirizine (16 %) was observed in a multiple dose study with theophylline (400 mg once a day); while the disposition of theophylline was not altered by concomitant cetirizine administration.

### *Ritonavir*

In a multiple dose study of ritonavir (600 mg twice daily) and cetirizine (10 mg daily), the extent of exposure to cetirizine was increased by about 40 % while the disposition of ritonavir was decreased (-11 %).

### *Food*

The extent of absorption of XYZAL is not reduced with food, although the rate of absorption is decreased.

### *Alcohol*

In sensitive patients the simultaneous administration of XYZAL and alcohol or other central nervous system (CNS) depressants may have effects on the central nervous system. It is advisable to avoid excessive alcohol consumption.

## **PREGNANCY AND LACTATION:**

XYZAL is contra-indicated in pregnancy as safety has not been demonstrated.

XYZAL is contra-indicated in women who are breastfeeding their babies, since the active ingredient is excreted in breast milk.

## **DOSAGE AND DIRECTIONS FOR USE:**

### **XYZAL FILM-COATED TABLET:**

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

**Adults and adolescents 12 years of age and older:**

The daily recommended dose is one 5 mg tablet.

**Elderly:**

Adjustment of the dose is recommended in elderly patients with moderate to severe renal impairment (see Patients with renal impairment below).

**Children:**

For children aged 2-6 years no adjusted dosage is possible with the film-coated tablet formulation. **It is recommended to use XYZAL ORAL SOLUTION (see WARNINGS AND SPECIAL PRECAUTIONS).**

*Children aged 6-12 years:*

The daily recommended dose is one 5 mg tablet.

**XYZAL ORAL SOLUTION:**

**Adults and adolescents 12 years of age and older:**

The daily recommended dose is 5 mg (10 ml) once daily.

**Elderly:**

Adjustment of the dose is recommended in elderly patients with moderate to severe renal impairment (see Patients with renal impairment below).

**Children:**

*Children aged less than 2 years:*

The administration of XYZAL to infants and toddlers aged less than 2 years is not recommended (see WARNINGS AND SPECIAL PRECAUTIONS).

*Children aged 2-6 years:*

The daily recommended dose 2,5 mg to be administered in 2 intakes of 1,25 mg (2,5 ml of solution twice daily).

*Children aged 6-12 years:*

The daily recommended dose is 5 mg (10 ml) once daily.

**Tablets and solution:**

***Adults with renal impairment:***

The dosing interval must be individualised according to renal function. Refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (CL<sub>cr</sub>) in ml/min is needed.

The CL<sub>cr</sub> (ml/min) may be estimated from serum creatinine (µmol/l) determination using the following formula:

$$CL_{cr} = \frac{[140 - \text{age (years)}] \times \text{weight (kg)}}{\text{serum creatinine (}\mu\text{mol/l)}} \quad (\times 0,85 \text{ for women})$$

**Dosing adjustments for patients with impaired renal function:**

Group	Creatine clearance (ml/min)	Dosage and frequency
Normal	≥ 80	5 mg once daily
Mild	50-79	5 mg once daily
Moderate	30-49	5 mg once every 2 days
Severe	< 30	5 mg once every 3 days
End-stage renal disease – patients undergoing dialysis	< 10	Contraindicated

***In paediatric patients suffering from renal impairment:***

The dose will have to be adjusted on an individual basis taking into account the renal clearance of the patient and his/her body weight. There are no specific data for children with renal impairment.

***Patients with hepatic impairment:***

No dose adjustment is needed in patients with solely hepatic impairment. In patients with hepatic impairment and renal impairment, adjustment of the dose is recommended (see Patients with renal impairment above).

***Duration of use:***

Intermittent allergic rhinitis (symptoms < 4 days/week or during less than 4 weeks) has to be treated according to the disease and its history; it can be stopped once the symptoms have disappeared and can be restarted again when symptoms reappear. In case of persistent allergic rhinitis (symptoms > 4 days/week or during more than 4 weeks), continuous therapy can be proposed to the patient during the period of exposure to allergens. Clinical experience with XYZAL film-coated tablet is currently available for a 6-month treatment period.

**SIDE EFFECTS:**

**Clinical trial data:**

In therapeutic studies in women and men aged 12 to 71 years, 15,1 % of the patients in the XYZAL 5 mg group had at least one adverse reaction.

In therapeutic trials, the dropout rate due to adverse events was 1,0 % (9/935) with XYZAL 5 mg. Clinical therapeutic trials with XYZAL included 935 subjects exposed to the medicine at the recommended dose of 5 mg daily.

Adverse reactions are ranked under headings of frequency using the following convention:

Very common  $\geq 1/10$

Common  $\geq 1/100$  to  $< 1/10$

Uncommon  $\geq 1/1\ 000$  to  $< 1/100$

Rare  $\geq 1/10\ 000$  to  $< 1/1\ 000$

Very rare  $< 1/10\ 000$

Not known (cannot be estimated from the available data).

***Immune system disorders:***

Not known: angioedema

***Nervous system disorders:***

Common: headache, somnolence

***Gastrointestinal disorders:***

Common: dry mouth

Uncommon: nausea and gastro-intestinal discomfort. Abdominal pain

***General disorders and administration site conditions:***

Common: fatigue

Uncommon: asthenia, malaise

***Skin and subcutaneous tissue disorders:***

In some individuals, hypersensitivity reactions including skin reactions, urticaria and pruritus may develop.

***Paediatric patients:***

In paediatric patients less than 6 years, 159 subjects were exposed to XYZAL at the dose of 1,25 mg daily for 2 weeks or 1,25 mg twice daily. The following incidence of side effects were reported under XYZAL.

***Psychiatric disorders:***

Common: sleep disorders

***Nervous system disorders:***

Common: somnolence

***Gastrointestinal disorders:***

Common: diarrhoea, constipation

Uncommon: vomiting.

In children aged 6-12 years double blind placebo controlled studies were performed where 243 children were exposed to 5 mg XYZAL daily for variable periods ranging from less than 1 week to 13 weeks. The following incidence of side effects were reported:

***Nervous system disorders:***

Common: somnolence

Uncommon: headache.

**Post-marketing data:**

In addition to the adverse reactions reported during clinical studies and listed above, the following side effects have been reported in post-marketing experience:

***Immune system disorders:*** hypersensitivity including anaphylaxis

***Metabolism and nutrition disorders:*** increased weight, increased appetite

***Psychiatric disorders:*** aggression, agitation, hallucination, depression, insomnia, suicidal ideation

***Nervous system disorders:*** convulsions, paraesthesia, dizziness, syncope, tremor, dysgeusia

***Eye disorders:*** visual disturbances, blurred vision

***Ear and labyrinth disorders:*** vertigo

***Cardiac disorders:*** palpitations, tachycardia

***Respiratory, thoracic and mediastinal disorders:*** dyspnoea

***Gastrointestinal disorders:*** nausea, vomiting

***Hepatobiliary disorders:*** hepatitis, abnormal liver function test

***Skin and subcutaneous tissue disorders:*** angioedema, fixed drug eruption, pruritus, rash, urticaria

***Musculoskeletal and connective tissue disorders:*** myalgia

***Renal and urinary disorders:*** dysuria, urinary retention

***General disorders and administration site conditions:*** oedema.

#### **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

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

There is no known specific antidote to XYZAL. Should overdose occur, symptomatic or supportive treatment is recommended. Levocetirizine is not effectively removed by haemodialysis.

#### **IDENTIFICATION:**

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

XYZAL ORAL SOLUTION: Clear and colourless solution.

#### **PRESENTATION:**

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 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.

**STORAGE INSTRUCTIONS:**

Store at or below 30 °C. Protect XYZAL film-coated tablets from moisture.

Keep out of reach of children.

**REGISTRATION NUMBER:**

XYZAL film-coated tablets: 36/5.7.1/0425

XYZAL ORAL SOLUTION: 41/5.7.1/0032

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:****Date of registration:**

XYZAL film-coated tablets: 28 May 2004

XYZAL ORAL SOLUTION: 27 January 2010

**Date of most recent revision:**

06 April 2017

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Botswana:

XYZAL: Reg No BOT0700949 **S2**

XYZAL ORAL SOLUTION: Reg No BOT0801102 **S2**

Namibia:

XYZAL: Reg No 04/5.7.1/1709 **NS1**

XYZAL ORAL SOLUTION: Reg No 10/5.7.1/0189 **NS1**

## Patient Information Leaflet

### SCHEDULING STATUS:

S2

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

XYZAL film-coated tablets

### XYZAL ORAL SOLUTION

Levocetirizine dihydrochloride 5 mg and 0,5 mg/ml, respectively

**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.
- Ask your 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 XYZAL CONTAINS:

The active substance is called levocetirizine dihydrochloride.

XYZAL tablets:

Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.

Contains sugar (63,50 mg lactose monohydrate per tablet).

Other ingredients are: colloidal anhydrous silica, hypromellose, macrogol 400, magnesium stearate, microcrystalline cellulose, titanium dioxide.

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.

Contains sugar (0,4 g maltitol per ml).

Other ingredients are: acetic acid, glycerol 85 %, purified water, saccharin sodium, sodium acetate, Tutti Frutti flavour (501103A7).

### **WHAT XYZAL 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).

### **BEFORE YOU TAKE XYZAL:**

#### **Do not take XYZAL:**

- if you or your child are hypersensitive (allergic) to levocetirizine dihydrochloride or any other substances with a similar chemical structure or to one of the other ingredients of XYZAL
- if you or your child have a severe impairment of kidney function
- if you are pregnant or breastfeeding your baby.

The use of XYZAL ORAL SOLUTION is not recommended for infants and children under 2 years of age.

#### **Take special care with XYZAL:**

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

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.

**Taking XYZAL with food and drink:**

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 and ability to drive and use machines.

**Pregnancy and breastfeeding:**

Do not use XYZAL if you are pregnant or breastfeeding your baby (see Do not take XYZAL).

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice, before taking XYZAL.

**Driving and using machinery:**

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.

**Important information about some of the ingredients of XYZAL:*****Tablets:***

XYZAL tablets contain lactose/fructose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take XYZAL tablets. Lactose may have an effect on the control of your blood sugar if you have diabetes mellitus.

***Solution:***

- 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).

### **Taking other medicines with XYZAL:**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

### **HOW TO TAKE XYZAL:**

Always take XYZAL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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 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.

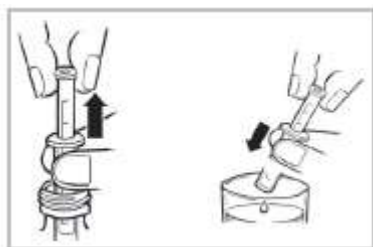
XYZAL can be taken with or without food.

**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 control 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.

## **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 healthcare professional 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 very 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.

**Less frequent side effects:**

- exhaustion
- abdominal pain
- 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

- liver inflammation, abnormal liver function and nausea and vomiting
- painful urination, inability to empty bladder.

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

#### **STORING AND DISPOSING OF 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.

#### **PRESENTATION OF XYZAL:**

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.

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**Date of most recent revision:**

06 April 2017

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## Pasiëntinligtingsbrosjure

### SKEDULERINGSSTATUS:

S2

### EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:

XYZAL filmbedekte tablette

XYZAL ORAL SOLUTION (Orale Oplossing)

Levosetirisiendihydrochloried 5 mg en 0,5 mg/ml, onderskeidelik

**Lees hierdie hele brosjure noukeurig deur omdat dit belangrike inligting vir jou bevat.**

XYZAL is sonder 'n dokter se voorskrif vir jou beskikbaar om 'n matige siekte te behandel.

Jy moet XYZAL nogtans versigtig gebruik om die beste resultate daaruit te verkry.

- Hou hierdie brosjure. Dit mag nodig wees dat jy dit weer moet lees.
- Vra jou apteker as jy nog inligting of raad nodig het.
- Jy of jou kind moet 'n dokter raadpleeg as julle simptome vererger of nie binne 14 tot 21 dae verbeter nie.

### WAT XYZAL BEVAT:

Die aktiewe bestanddeel word levosetirisiendihydrochloried genoem.

XYZAL tablette:

Elke filmbedekte tablet bevat 5 mg levosetirisiendihydrochloried.

Bevat suiker (63,50 mg laktosemonohidraat per tablet).

Ander bestanddele is: kolloïdale anhidriese silika, hipromellose, makrogol 400, magnesiumstearaat, mikrokristallyne sellulose, titaandioksied.

XYZAL ORAL SOLUTION:

Elke 1 ml orale oplossing bevat 0,5 mg levosetirisiendihydrochloried.

Bevat as preserveermiddels: 0,675 mg metiel parahidroksibensoaat per ml en 0,075 mg propiel parahidroksibensoaat per ml.

Bevat suiker (0,4 g maltitol per ml).

Ander bestanddele is: asynsuur, 85 % gliserol, gesuiwerde water, natriumsakaraat, natriumasetaat, Tutti Frutti-geursel (501103A7).

#### **WAARVOOR XYZAL GEBRUIK WORD:**

Die aktiewe bestanddeel, levosetirisiendihydrochloried, is 'n antihistamien vir sistemiese gebruik. Dit word gebruik vir die behandeling van tekens van siekte (simptome) wat verband hou met:

- allergiese rinitis (waaronder aanhoudende allergiese rinitis)
- chroniese brandneteluitslag van onbekende oorsprong (chroniese idiopatiese urtikarie).

#### **VOORDAT JY XYZAL GEBRUIK:**

##### **Jy moenie XYZAL drink nie:**

- as jy of jou kind hipersensitief (allergies) is vir levosetirisiendihydrochloried of enige ander stof met 'n soortgelyke chemiese struktuur of een van die ander bestanddele van XYZAL
- as jy of jou kind erge swak nierfunksie het
- as jy swanger is of jou baba borsvoed.

Die gebruik van XYZAL ORAL SOLUTION word nie aanbeveel vir babas en kinders onder 2 jaar oud nie.

#### **Wees besonder versigtig met XYZAL:**

Die gebruik van XYZAL-tablette word nie vir kinders van jonger as 6 jaar aanbeveel nie.

Wees veral versigtig indien jy predisponerende faktore vir urienretensie het (onvermoë om die blaas heeltemal leeg te maak) (bv. rugmurgletsels, prostaathiperplasie (vergrande prostaat)), aangesien XYZAL die risiko vir urienretensie kan verhoog.

#### **Gebruik van XYZAL saam met voedsel en drank:**

Jy kan XYZAL met of sonder voedsel drink. XYZAL filmbedekte tablette moet met vloeistof gedrink word. Wees versigtig as XYZAL saam met alkohol gedrink word. In sensitiewe pasiënte kan die gelyktydige gebruik van XYZAL en alkohol of middels wat die sentrale senuweestelsel beïnvloed, effekte hê op wakkerheid en die vermoë om 'n voertuig te bestuur of masjiene te gebruik.

#### **Swangerskap en borsvoeding:**

Moenie XYZAL gebruik as jy swanger is of jou baba borsvoed nie (kyk Jy moenie XYZAL drink nie).

As jy swanger is of jou baba borsvoed, moet jy asseblief jou dokter, apteker of ander gesondheidsorgkundige om advies vra voordat jy XYZAL drink.

#### **Motorbestuur en gebruik van masjinerie:**

Sommige pasiënte wat met XYZAL behandel word, kan slaperigheid/lomerigheid, moegheid en uitputting ervaar. As jy van voorneme is om 'n voertuig te bestuur, by moontlike gevaarlike aktiwiteite betrokke wil raak of masjinerie wil gebruik, word jy dus aangeraai om eers te wag en te kyk wat jou reaksie op XYZAL is.

#### **Belangrike inligting oor sommige van die bestanddele van XYZAL:**

##### ***Tablette:***

XYZAL-tablette bevat laktose/fruktose. Pasiënte met die seldsame oorerflike toestand van onverdraagbaarheid van laktose/fruktose of galaktose moet nie XYZAL-tablette drink nie.

Laktose kan 'n effek op die beheer van jou bloedsuiker hê as jy diabetes mellitus het.

**Oplossing:**

- XYZAL ORAL SOLUTION bevat maltitol. As vir jou gesê is dat jy 'n onverdraagbaarheid teenoor sekere suikers het, moet jy nie XYZAL ORAL SOLUTION drink nie.
- Metiel parahidroksibensoaat en propiel parahidroksibensoaat kan allergiese reaksies veroorsaak (moontlik vertraag).

**Gebruik van ander medisyne saam met XYZAL:**

Sê altyd vir jou gesondheidsorgkundige as jy enige ander medisyne gebruik. (Dit sluit aanvullende of tradisionele medisyne in.)

**HOE OM XYZAL TE DRINK:**

Gebruik XYZAL altyd presies soos wat jou dokter aan jou gesê het. Raadpleeg jou dokter of apteker as jy nie seker is nie.

Die gewone dosis is:

**Volwassenes en kinders van 6 jaar en ouer:**

- XYZAL filmbedekte tablette: Die aanbevole daaglikse dosis is een tablet. Die tablette moet heel met water afgesluk word en kan met of sonder voedsel gedrink word.
- XYZAL ORAL SOLUTION: Die aanbevole daaglikse dosis is 10 ml (twee medisynemate) een keer per dag.

**Kinders van 2 tot 6 jaar oud:**

- XYZAL ORAL SOLUTION: 2,5 ml oplossing twee keer per dag.

Die toediening van XYZAL aan babas en kleuters onder die ouderdom van 2 jaar word nie aanbeveel nie.

Praat met jou dokter of apteker as jy die indruk het dat die effek van XYZAL te sterk of te swak is.

### **Aanwysings vir die gebruik van XYZAL-oplossing:**

Slegs vir orale gebruik.

'n Doseerspuit word by die verpakking ingesluit (kyk in die diagram hoe om dit te gebruik).

Die oplossing kan onverdund gedrink word of verdun in 'n glas water.

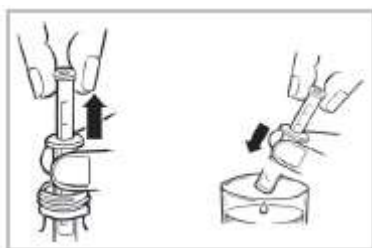
XYZAL kan met of sonder voedsel gedrink word.

### **Gebruik van die doseerspuit:**

Druk die doseerspuit in die bottel en trek die suier tot by die merk wat ooreenstem met die dosis in milliliter (ml) wat deur jou dokter voorgeskryf is. Vir gebruik deur kinders jonger as 6 jaar word die daaglikse dosis van 5 ml verkry deur 2,5 ml oplossing twee keer per dag uit die bottel te neem (kyk asseblief noukeurig na die gradering op die spuit).

Haal die doseerspuit uit die bottel en spuit die inhoud in 'n lepel of in 'n glas water deur die suier af te druk. Die medisyne moet net na verdunning gedrink word.

Spoel die suier na elke gebruik met water uit.



### **As jy meer XYZAL gedrink het as wat jy moes:**

As jy meer XYZAL drink as wat jy moet, kan lomerigheid in volwassenes voorkom. Kinders kan aanvanklik eksitasie en rusteloosheid toon gevolg deur lomerigheid.

Raadpleeg jou dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kry hulp van die naaste hospitaal of vergiftigingsentrum.

### **As jy vergeet om XYZAL te drink:**

Moenie 'n dubbele dosis drink om vir vergete individuele dosisse op te maak nie, gaan net voort en drink die hoeveelhede wat in die doseerinstruksies aangedui word.

### **Effekte wanneer behandeling met XYZAL gestaak word:**

As behandeling met XYZAL vroeër as wat voorsien is gestaak word, sal dit geen nadelige effekte hê nie.

### **MOONTLIKE NEWE-EFFEKTE:**

XYZAL kan newe-effekte veroorsaak.

Nie al die newe-effekte wat vir XYZAL aangemeld is, is in hierdie brosjure opgeneem nie. As jou algemene gesondheidstoestand vererger of as jy newe-effekte ervaar terwyl jy XYZAL drink, moet jy jou dokter, apteker of ander gesondheidsorgkundige om advies raadpleeg.

Indien enige van die volgende voorkom, moet jy ophou om XYZAL te gebruik en onmiddellik vir jou dokter sê of na die ongevalle-afdeling van jou naaste hospitaal gaan:

- swelling van die mond, tong, gesig en/of keel wat probleme met asemhaling of sluk kan veroorsaak
  - veluitslag of jeuk
  - skielike val in bloeddruk wat tot ineenstorting of skok kan lei, wat dodelik kan wees.
- Dit is almal baie ernstige newe-effekte. As jy dit ervaar, kan dit wees dat jy 'n baie ernstige allergiese reaksie teenoor XYZAL het. Dit mag wees dat jy dringende mediese aandag of hospitalisasie nodig het.

Ander newe-effekte is onder meer:

**Algemene newe-effekte:** droë mond, hoofpyn, moegheid en lomerigheid/slaperigheid.

**Minder gereelde newe-effekte:**

- uitputting
- buikpyn

- onreëlmatige hartklop, toevalle, visiesteurnisse, floutes, bewerasie, abnormale smaak, duiseligheid
- swelling, pruritus (jeuk), veluitslag, urtikarie (swelling, rooiheid en jeuk van die vel)
- kortasemheid, gewigstoename, groter eetlus, spierpyn, aggressiewe of geagiteerde gedrag, slaaploosheid, selfmoordgedagtes
- lewerontsteking, abnormale lewerfunksie en naarheid en braking
- pynlike urinering, onvermoë om blaas te ledig.

As jy enige nuwe-effekte opmerk wat nie in hierdie blad genoem word nie, moet jy jou dokter of apteker asseblief in kennis stel.

#### **BEWARING EN WEGDOENING VAN XYZAL:**

Hou alle medisyne buite bereik van kinders.

Bewaar by of benede 30 °C.

Beskerm XYZAL-tablette teen vog.

Hierdie medisyne moet nie na die vervaldatum op die etiket gebruik word nie.

Gee alle ongebruikte medisyne terug aan jou apteker.

Moenie ongebruikte medisyne in dreinerings- of rioolstelsels, bv. toilette, gooi nie.

#### **AANBIEDING VAN XYZAL:**

XYZAL filmbedekte tablette word in stolpstroke (poliamied/aluminium/PVC-kompleks met 'n bedekking van aluminiumfoelie wat kan deurdruk of 'n poliamied/aluminium/PVC-kompleks met bedekkingsmateriaal van papiergesteunde aluminiumfoelie) met 7 of 10 tablette verpak.

1 strook (7 of 10 tablette) of 3 stroke (30 tablette) is in kartondose verpak.

XYZAL ORAL SOLUTION is verpak in amber glasbottels met 75 ml of 150 ml oplossing en met wit kindbestande polipropileenproppe. Dit word verpak in 'n kartonhouer met 'n gegradeerde spuit vir orale dosering.

**IDENTIFIKASIE VAN XYZAL:**

XYZAL filmbedekte tablette: Wit tot naaswit, ovaal filmbedekte tablet met 'n Y-logo aan die een kant.

XYZAL ORAL SOLUTION: Helder en kleurlose vloeistof.

**REGISTRASIENOMMER:**

XYZAL filmbedekte tablette: 36/5.7.1/0425

XYZAL ORAL SOLUTION: 41/5.7.1/0032

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XYZAL filmbedekte tablette: 28 Mei 2004

XYZAL ORAL SOLUTION: 27 Januarie 2010

**Datum van mees onlangse hersiening:**

06 April 2017

Handelsmerke is in besit van of gelisensieer aan die GSK-groep van maatskappye.

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