APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

TEXAMER SYRUP oral solution

Levocetirizine dihydrochloride

Contains preservative sodium benzoate 0,4 % m/v

Contains maltitol liquid 400 mg/ml

Contains sweeteners glycerol 230 mg/ml and saccharin sodium 2 mg/ml

Read all of this leaflet carefully before you start taking TEXAMER SYRUP

TEXAMER SYRUP is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use TEXAMER SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share TEXAMER SYRUP with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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1. What TEXAMER SYRUP is and what it is used for

TEXAMER SYRUP contains levocetirizine dihydrochloride, which is an allergic agent. TEXAMER SYRUP is used to treat symptoms associated with allergic conditions such as:

- hayfever
- year-round allergies such as dust or pet allergies
- nettle rash (urticaria).

2. What you need to know before you take TEXAMER SYRUP

Do not take TEXAMER SYRUP:

- if you are hypersensitive (allergic) to levocetirizine, or to other antihistamines called piperazine derivatives (such as buclizine, cetirizine, cyclizine), or any of the other ingredients of TEXAMER SYRUP (see section 6)
- if you are pregnant, intend to become pregnant, or are breastfeeding your baby
- if you suffer from severe kidney failure (with creatinine clearance below 10 ml/min)
- Do not give TEXAMER SYRUP to children younger than 2 years.

Warnings and precautions

Take special care with TEXAMER SYRUP

- if you are likely to be unable to empty your bladder (due to conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice
- if you suffer from epilepsy or are at risk of convulsions, ask your doctor for advice as use of TEXAMER SYRUP may cause seizure to be severe or occur more frequently
- if you are going for allergy testing, you should stop taking TEXAMER SYRUP for at least 3 days before testing as TEXAMER SYRUP will affect your allergy test results

- when you stop taking TEXAMER SYRUP, you may experience itchy skin, even if it was not present before starting treatment. The itching may stop on its own, but in some cases, you experience intense itching and may need to restart treatment with TEXAMER SYRUP.

Children

Do not give TEXAMER SYRUP to children less than 2 years because it is unlikely to be safe.

Other medicines and TEXAMER SYRUP

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

Please consult your healthcare provider for advice if you are taking any of the following medicine:

- theophylline, used to treat asthma and lung conditions, and ritonavir, used to treat HIV. These may increase the amount of TEXAMER SYRUP in your body which increases the risk of side effects.

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TEXAMER SYRUP with food, drink and alcohol

TEXAMER SYRUP may be taken with or without food.

Caution is advised if TEXAMER SYRUP is taken at the same time with alcohol or other agents acting on the brain. (see Take special care with TEXAMER SYRUP).

In sensitive patients, TEXAMER SYRUP taken together with alcohol or other medicines acting on the brain may cause increase the side effects of levocetirizine such as dizziness, drowsiness and difficulty concentrating. Some people may also experience reduced alertness, impairment in thinking and judgement. You should avoid or limit the use of alcohol while being treated with TEXAMER SYRUP.

Pregnancy, breastfeeding and fertility

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

Driving and using machines

TEXAMER SYRUP lacks significant sedative effects, however, you may experience drowsiness, tiredness and fatigue which may affect your ability to drive and use machines.

It is not always possible to predict to what extent TEXAMER SYRUP may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which TEXAMER SYRUP affects you.

TEXAMER SYRUP contains maltitol liquid

TEXAMER SYRUP contains maltitol liquid and may have a laxative effect. If you have been told that you have an intolerance to some sugars, you should not take TEXAMER SYRUP.

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3. How to take TEXAMER SYRUP

Do not share medicines prescribed for you with any other person. Always take TEXAMER SYRUP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children from the age of 6 years

The usual dose is 10 ml solution once daily.

Children from the age of 2 to 6 years

The usual dose is 2,5 ml solution twice daily.

Do not give TEXAMER SYRUP to infants and toddlers aged less than 2 years.

Special dosage instructions for specific populations

Kidney and liver problems

If you have impaired kidney function you may be given a lower dose according to the severity of your kidney condition. Your doctor or pharmacist will determine the dose.

If you have only impaired liver function you should take the usual prescribed dose.
If you have both impaired liver and kidney function you may be given a lower dose depending on the severity of the kidney condition. The dose in children will also be chosen on the basis of body weight by your doctor.

Elderly patients aged 65 years and above

No adaptation of the dose is necessary in elderly patients, provided their renal function is normal.

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How and when should you take TEXAMER SYRUP

This medicine is for oral use only.

A dosing syringe is provided with the pack. You can take TEXAMER SYRUP with or without food.

Handling of the dosing syringe

Place the dosing syringe into the bottle and draw the plunger up to the mark which corresponds to the dose in millilitres (ml) prescribed by your doctor.

Remove the dosing syringe from the bottle and empty its contents into a spoon by pressing the plunger down. Rinse the plunger with water after every use.

If you take more TEXAMER SYRUP than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include

- drowsiness can occur in adults
- children may initially show a sense of excitement (agitation) and restlessness followed by drowsiness.

If you forget to take TEXAMER SYRUP

If you forget to take TEXAMER SYRUP, take your next dose at your normal time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TEXAMER SYRUP

Stopping treatment should have no negative effects. However, rarely, you may experience intense itching (pruritus) if you stop taking TEXAMER SYRUP, even if those symptoms were not present before you started treatment. 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

TEXAMER SYRUP can have side effects.

Not all side effects reported for TEXAMER SYRUP are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while taking TEXAMER SYRUP, please consult your healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- thinking about or feeling like you want to take your own life
- strong or irregular heartbeat, abnormally rapid heart rate
- difficulty breathing
- painful or difficult urination, passing less urine than is normal for you
- seizures (fits)

- liver infection (hepatitis) characterized by abdominal pain especially on the upper right side beneath your lower rib, dark urine, fever, yellowing of skin and eyes, which is sore when you press it (tenderness) on the right side just below your ribs and clay-coloured stool
- intense itching upon discontinuation.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following

Frequent side effects

- headache
- sleepiness or drowsiness
- dry mouth
- diarrhoea
- constipation
- tiredness
- sleep disorders.

Less frequent side effects

- nausea, abdominal pain
- abnormal physical weakness or lack of energy
- general feeling of discomfort

Side effects with unknown frequency

- weight gain, increased appetite
- aggression, agitation, seeing or hearing things that are not there (hallucination), depression, difficulty in falling and staying asleep (insomnia), nightmares
- tingling or prickling sensation (pins and needles), involuntary shaking (tremors), dizziness,

distortion of sense of taste (dysgeusia)

- changes in vision, blurred vision
- sensation of spinning or feeling off balance
- vomiting
- swelling, redness and itchiness of the skin (urticaria)
- muscle pain, joint pain
- general swelling of ankles, feet and legs (oedema).

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 TEXAMER SYRUP.

5. How to store TEXAMER SYRUP

Store all medicines out of reach of children.

Store at or below 25 °C. Keep the bottle tightly closed.

Store in the original package to protect from light.

Do not use 3 months after first opening.

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

Return all unused medicine to your pharmacist.

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

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6. Contents of the pack and other information

What TEXAMER SYRUP contains

The active substance is levocetirizine dihydrochloride.

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

Contains preservative sodium benzoate 0,4 % *m/v*.

Contains maltitol 400 mg/ml.

Contains sweeteners glycerol 230 mg/ml and saccharin sodium 2 mg/ml.

The other ingredients are acetic acid glacial (for pH adjustment), glycerol, maltitol liquid, saccharin sodium, sodium acetate trihydrate (for pH
adjustment), sodium benzoate, wild strawberry aroma (flavouring substances,
natural flavouring substances, propylene glycol), water purified.

What TEXAMER SYRUP looks like and contents of the pack

TEXAMER SYRUP is a clear and colourless oral solution, essentially free from particles, with a wild strawberry-like smell and flavour.

TEXAMER SYRUP is packed into a 200 ml, type III brown glass bottle, closed with a polyethylene screw cap with a child-resistant closure with a tamper evident security ring. The bottle and graduated oral syringe are packed into a unit carton.

The graduated oral syringe is a cylindrical device with movable plunger and consist of 3 parts (barrel, plunger and piston). The barrel and piston are made from colourless polyethylene LDPE and the plunger from white polystyrene.

Holder of Certificate of Registration

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