PATIENT INFORMATION LEAFLET

TEXAMER

SCHEDULING STATUS

S1

TEXAMER film coated tablets

Levocetirizine dihydrochloride

TEXAMER contains sugar (lactose 92,50 mg)

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

- TEXAMER is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use TEXAMER carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share TEXAMER 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 after 5 days.

What is in this leaflet

1. What TEXAMER is and what it is used for
2. What you need to know before you use TEXAMER
3. How to use TEXAMER
4. Possible side effects
5. How to store TEXAMER
6. Contents of the pack and other information

1. What TEXAMER is and what it is used for

TEXAMER is an anti-allergic medicine.

TEXAMER is indicated for the relief of symptoms associated with the following allergic conditions in adults:

- Seasonal allergic irritation and inflammation of the nose.
- Allergic irritation and inflammation of the nose throughout the year.
- Daily, long term allergic irritation of the skin (chronic nettle rash of unknown origin -- chronic idiopathic urticaria).

2. What you need to know before you take TEXAMER

Do not take TEXAMER:

- if you or your child are hypersensitive (allergic) to levocetirizine, or to any of the ingredients of TEXAMER (see section 6).
- If you or your child are hypersensitive to medicines containing a substance derived from piperazine. These substances could be in heart medicines, antidepressants, antipsychotic medicines or sexual enhancement medicines. Refer to your doctor for advice.
- If you or your child have a severe kidney disease.
- If you or your child are on dialysis.
- If you are pregnant or breastfeeding your baby.
- Do not give TEXAMER to children under the age of 6 years.

Warnings and precautions

Take special care with TEXAMER:

- TEXAMER may make you sleepy.
- Caution is advised if TEXAMER is taken at the same time as alcohol. In sensitive patients, the simultaneous use of TEXAMER and alcohol or medicines affecting the central nervous system may have effects on alertness and ability to drive and use machines.

- 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 TEXAMER may increase the risk of urinary retention.
- If you suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of TEXAMER may cause seizure aggravation.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking TEXAMER for several days before testing. This medicine may affect your allergy test results.
- Pruritus (intense itching) and/or urticaria may occur if you stop taking TEXAMER.
- TEXAMER is not suitable for children under the age of 6 (see Do not take TEXAMER).

Other medicines and TEXAMER

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

Caution is advised if TEXAMER is taken at the same time as alcohol (see Take special care).

Tell your doctor if you are taking:

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

TEXAMER with food and drink

TEXAMER may be taken with or without food.

It is advisable to avoid excessive alcohol consumption while taking TEXAMER at the same time, as the effect of TEXAMER may be increased or may be different than expected (see Take special care).

Pregnancy, breastfeeding and fertility

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 professional for advice before using TEXAMER.

You should not take TEXAMER while you are pregnant or breastfeeding your baby, as safety has not been demonstrated.

The active ingredient is excreted in breastmilk.

Driving and using machines

Caution is advised when driving or using heavy machinery, as TEXAMER may cause drowsiness and fatigue.

It is not always possible to predict to what extent TEXAMER may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TEXAMER affects them.

Important information about some of the ingredients of

TEXAMER

TEXAMER contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take TEXAMER.

TEXAMER contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take TEXAMER

Do not share medicines prescribed for you with any other person. Always take TEXAMER 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 filmcoated tablet must be taken orally, swallowed with liquid and it is recommended to take the daily dose in one single intake.

Adults or children 12 years of age or older:

The usual dose is one 5 mg tablet.

Patients with liver disease:

No change in dosage is needed in patients with liver disease.

Patients with kidney disease: (speak to your doctor for advice)

Patients with mild or moderate kidney disease may take TEXAMER only every second or third day respectively. If you have a severe kidney disease you should not take TEXAMER at all. (See Do not take TEXAMER.)

Elderly patients:

No adjustment of the dose is necessary in elderly patients with normal kidney function, however, in those elderly patients with moderate or severe kidney disease, your doctor will adjust your dose.

Children

Children 6 - 12 years:

The recommended daily dose is one 5 mg tablet.

Children 2 - 6 years:

TEXAMER is not indicated in children under the age of 6 (see Do not take).

If you have the impression that the effect of TEXAMER is too strong or too weak, tell your doctor or pharmacist.

If you take more TEXAMER 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.
- Overdosage in children may produce restlessness or agitation followed by drowsiness.

If you forget to take TEXAMER

If you forget to take TEXAMER, take as soon as you remember on the same day. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TEXAMER

Stopping treatment should have no negative effects. However, rarely pruritus (intense itching) may occur if you stop taking TEXAMER, 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 can have side effects.

Not all side effects reported for TEXAMER are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using TEXAMER, please consult your healthcare provider for advice.

If any of the following happens, stop using TEXAMER 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. 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:

- irregular and/or fast heartbeat

- shortness of breath or difficulty breathing
- if your liver function test came back abnormal or if your liver is inflamed (symptoms may include stomach pain or yellowing of the skin and whites of the eyes (jaundice)
- serious skin reactions (hives and/or itchy skin)
- convulsions (fits)
- hallucinations (seeing or hearing things that are not there), depression, suicidal thoughts
- inability to completely empty the bladder

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:

- difficulty sleeping
- headaches, sleepiness
- dry mouth, diarrhea, constipation
- fatigue

Less frequent side effects:

- nausea, stomach pains or discomfort
- feeling tired, weak or generally unwell, abnormal physical weakness or lack of energy

The following side effects have been reported but the frequency for them to occur is not known:

- increased weight, increased appetite
- feeling aggressive, agitated, nightmares
- tingly or numbness sensation of the skin, dizziness, distortion of the sense of taste

- blurry vision or visual disturbances (difficulty to see), uncontrolled circular movements of the eyes
- vertigo (sensation of whirling and loss of balance)
- vomiting
- muscle aches
- hives or skin eruptions in the same place, itching
- painful urination
- swelling caused by excess fluid trapped in your body's tissues (generally in the hands, arms, feet, ankles and legs)

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, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8. or http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/

By reporting side effects, you can help provide more information on the safety of TEXAMER. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store TEXAMER

Store all medicines out of reach of children.

Store at or below 30 °C

Protect from moisture.

Keep blisters in carton until required for use.

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).

6. Contents of the pack and other information

What TEXAMER contains

The active substance is levocetirizine dihydrochloride 5 mg.

The other ingredients are:

Tablet cores:

Colloidal silica anhydrous, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

Film coating Opadry white:

Hypromellose 6cP, lactose monohydrate, macrogol 3000, titanium dioxide, triacetin.

What TEXAMER looks like and contents of the pack

White, round, biconvex film coated tablets, 7 mm in diameter, with bevelled edges.

TEXAMER is packed into two different blister strips:

- OPA/Al/PVC and aluminium foil blister strips
- 7 or 10 tablets are packed into a blister strip
- 1 blister strip of 7 tablets is packed into an outer carton
- 1 or 3 blister strips of 10 tablets are packed into an outer carton.

Not all pack sizes and pack types are marketed.

Holder of Certificate of Registration

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