

## PATIENT INFORMATION LEAFLET

### TEXAMER

#### SCHEDULING STATUS:

S2
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#### PROPRIETARY NAME AND DOSAGE FORM:

**TEXAMER** film-coated tablets

**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 pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

#### 1. WHAT TEXAMER CONTAINS:

The active substance is levocetirizine dihydrochloride.

The other ingredients are colloidal silica anhydrous, lactose monohydrate, magnesium stearate, microcrystalline cellulose and Opadry white.

**TEXAMER** contains sugar (lactose monohydrate 92,50 mg/tablet).

#### 2. WHAT TEXAMER IS USED FOR:

**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.

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- Daily, long term allergic irritation of the skin.

### 3. BEFORE YOU TAKE TEXAMER:

#### Do not take TEXAMER:

- If you are hypersensitive (allergic) to levocetirizine or any of the other ingredients of **TEXAMER** (see **WHAT TEXAMER CONTAINS**).
- If you 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 have a severe kidney disease.
- If you are on dialysis.
- If you are pregnant or breastfeeding your baby.
- If you have been told by your doctor that you have an intolerance to some sugars
- Do not give **TEXAMER** to children.

#### 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.

#### Taking TEXAMER with food and drink:

- **TEXAMER** may be taken with or without food.

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- 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 and Breastfeeding:**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **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 machinery:**

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

**Important information about some of the ingredients of TEXAMER:**

**TEXAMER** contain lactose monohydrate; if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **TEXAMER**.

**Taking other medicines with TEXAMER:**

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

No interaction studies have been done with the active ingredient, levocetirizine.

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

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**4. HOW TO TAKE TEXAMER:**

Do not share medicines prescribed for you with any other person.

You should check with your doctor or pharmacist if you are unsure of how to take

**TEXAMER.**

The film-coated 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**".)

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 an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Drowsiness is an expected symptom of overdose.

Overdose in children may produce restlessness or agitation followed by drowsiness.

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**If you forget to take a dose of TEXAMER:**

Take the tablet when you remember and carry on with normal directions of use from the next day. Do not take a double dose to make up for a forgotten dose.

**5. 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 taking this medicine, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking **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 heart beat
- 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))

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- serious skin reactions (hives and/or itchy skin)
- convulsions (fits)

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

Tell your doctor if you notice any of the following:

- increased weight
- difficulty sleeping, feeling aggressive, agitated, depressed or having hallucinations
- headaches, sleepiness, prickly, tingly or numbness sensation of the skin, dizziness
- blurry vision or visual disturbances (difficulty to see)
- dry mouth, diarrhoea or constipation, nausea, vomiting or stomach pains
- hives or skin eruptions in the same place, itching
- muscle aches
- painful urination
- feeling tired, weak or generally unwell

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

**6. STORING AND DISPOSING OF TEXAMER:**

Store at or below 25 °C

Protect from moisture

Keep blister strip in carton until required for use

Do not use after the expiry date printed on the label or carton

Return all unused medicine to your pharmacist

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

**STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**