PATIENT INFORMATION LEAFLET

TEXA ALLERGY TABLETS

SCHEDULING STATUS

S1

TEXA ALLERGY TABLETS

Cetirizine dihydrochloride

TEXA ALLERGY TABLETS contains sugar (lactose monohydrate 117,0 mg)

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

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

- Keep this leaflet. You may need to read it again.
- Do not share TEXA ALLERGY TABLETS 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 7 days.

What is in this leaflet

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

1. What TEXA ALLERGY TABLETS is and what it is used for

TEXA ALLERGY TABLETS belongs to a group of medicines called long-acting non-sedating antihistamines.

TEXA ALLERGY TABLETS is used for the relief of allergic conditions such as:

- allergic rhinitis (allergy related stuffy or runny nose, sneezing) and hay fever
- allergic skin conditions such as urticaria (rash of round, red weals on the skin which itch intensely, sometimes with dangerous swelling, caused by an allergic reaction).

2. What you need to know before you take TEXA ALLERGY TABLETS

Do not take TEXA ALLERGY TABLETS:

- if you are hypersensitive (allergic) to cetirizine, hydroxyzine, piperazine or any other antihistamines, or to any of the ingredients of TEXA ALLERGY TABLETS (see section 6)
- if you have severe kidney disease
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding)
- if you suffer from asthma and have previously experienced side effects to antihistamines
- children under the age of two years should not be given TEXA ALLERGY TABLETS, as safety and efficacy have not been demonstrated.

Warnings and precautions

Take special care with TEXA ALLERGY TABLETS:

- TEXA ALLERGY TABLETS is a non-sedating medicine, however some patients may become drowsy after taking the tablets (see Driving and using machinery)
- when taking TEXA ALLERGY TABLETS alcohol should not be consumed (see Taking TEXA ALLERGY TABLETS with food and drink)
- if you have any condition that results in urinary retention (difficulty in emptying your bladder)
- if you are an epileptic patient (have fits), or a patient at risk of convulsions
- if you are scheduled for allergy testing, you should stop taking TEXA ALLERGY TABLETS at least 3 days before testing, since it may affect your allergy test results
- if you are elderly, you are more likely to experience side effects of TEXA ALLERGY TABLETS
- children under the age of six years should not be given TEXA ALLERGY TABLETS, as the tablet formulation does not allow for appropriate dose adaptation.

Children and adolescents

Do not give TEXA ALLERGY TABLETS to children under the age of 2 years, as the safety and efficacy have not been demonstrated.

Other medicines and TEXA ALLERGY TABLETS

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

- taking any other medicines that may make you drowsy (sedatives, tranquilisers or strong painkillers) with TEXA ALLERGY TABLETS is not advised
- as with other antihistamines it is advisable to avoid excessive alcohol consumption.

TEXA ALLERGY TABLETS with food and drink

TEXA ALLERGY TABLETS can be taken with or without meals. Alcohol should be avoided.

Pregnancy, breastfeeding and fertility

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

Driving and using machines

TEXA ALLERGY TABLETS can cause drowsiness and you should exercise caution before driving, operating hazardous machinery or performing hazardous tasks.

It is not always possible to predict to what extent TEXA ALLERGY TABLETS 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 TEXA ALLERGY TABLETS affects them.

TEXA ALLERGY TABLETS contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TEXA ALLERGY TABLETS.

3. How to take TEXA ALLERGY TABLETS

Do not share medicines prescribed for you with any other person. Always take TEXA ALLERGY TABLETS exactly as instructed in this leaflet. You should check with your doctor or pharmacist if you are not sure.

TEXA ALLERGY TABLETS should be swallowed with a glass of liquid.

Adults or children 12 years of age or older:

The usual dose is 10 mg (one tablet) once daily.

Children 6 - 12 years old:

The usual dose is 5 mg (half a tablet) twice daily or 10 mg (one tablet) once daily.

If you have a kidney or liver disorder, you should take 5 mg (half a tablet) once daily.

The duration of treatment depends on the type, duration and course of your symptoms. Please ask your doctor or pharmacist for advice.

If you take more TEXA ALLERGY TABLETS 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:

- confusion, diarrhoea, dizziness, headache, general unwell feeling, dilated pupils, restlessness,

drowsiness, stunned state in which it is difficult to get a response, feeling sleepy or tired, agitated, skin rash, passing less urine than is normal for you, uncontrolled trembling or shaking, and rapid heart rate.

If you forget to take TEXA ALLERGY TABLETS

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take TEXA ALLERGY TABLETS at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TEXA ALLERGY TABLETS

When stopping treatment with TEXA ALLERGY TABLETS, you may experience severe itching or raised bumps on the skin. If this occurs, restart treatment with TEXA ALLERGY TABLETS, and the side effects should stop.

4. Possible side effects

TEXA ALLERGY TABLETS can have side effects.

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

If any of the following happens, stop using TEXA ALLERGY TABLETS 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 TEXA ALLERGY TABLETS. 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:

- seizures (fits)
- fast or irregular heartbeat
- thoughts of killing yourself (suicidal ideation)
- yellowing of the skin and eyes (jaundice), nausea, stomach pain, fatigue and fever; signs of a liver problem
- passing less urine than normal.

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:

- sore throat, runny and itchy nose and sneezing.

Less frequent side effects:

- anaemia with symptoms such as fatigue, pale skin, abnormal blood test results
- bleeding and bruising easily
- feeling sleepy or drowsy, depression, confusion, aggression, agitation, hallucinations (seeing and hearing things that aren't there), inability to sleep (insomnia)
- twitching, uncontrolled trembling or shaking
- unusual tiredness or weakness, generally feeling unwell, discomfort or unease, fluid retention
- blurred or double vision, eye strain, difficulty focusing, rolling of the eyes
- vertigo (feeling unbalanced/spinning head), ringing or buzzing in the ears (tinnitus)
- low blood pressure (light-headedness, dizziness)
- a wheezing sound when you inhale, thickening of mucous (phlegm)

- diarrhoea, abdominal pain, bloating, excess gas (wind), nausea, constipation, dry mouth
- abnormal liver test results
- skin rashes or other skin conditions such as itchy or red skin, or sensitivity to light
- hair loss, sweating
- muscle pain
- pain or discomfort when urinating
- wetting the bed, especially by children at night
- weight gain.

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

- increased appetite
- headache, dizziness
- anxiety, nervousness, memory loss
- nightmares
- sensations of tingling, burning, pricking (pins and needles), or numbness of the skin
- bad taste in the mouth
- tremors (uncontrolled shaking)
- rash with blisters containing pus
- joint pain.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on

the safety of TEXA ALLERGY TABLETS. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of TEXA ALLERGY TABLETS.

5. How to store TEXA ALLERGY TABLETS

Store all medicines out of reach of children.

Store at or below 25 ºC, in a dry place.

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 TEXA ALLERGY TABLETS contains

The active substance is cetirizine dihydrochloride.

TEXA ALLERGY TABLETS contains cetirizine dihydrochloride 10 mg.

The other ingredients are:

Crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose and silica colloidal anhydrous.

The film coating contains hypromellose, titanium dioxide and polyethylene glycol/macrogol.

What TEXA ALLERGY TABLETS looks like and contents of the pack

Film coated, white to off-white convex, elliptical tablets scored on one side.

TEXA ALLERGY TABLETS are packed in aluminium/PVC blister packs of 10, 30 or 500 tablets, contained in a printed outer carton.

Holder of Certificate of Registration

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