PATIENT INFORMATION LEAFLET

TEXA ALLERGY SYRUP

SCHEDULING STATUS

S1

TEXA ALLERGY SYRUP 1 mg per mL

Cetirizine dihydrochloride

TEXA ALLERGY SYRUP contains no sugar (sucrose)

Contains sweetener: saccharin sodium 1 mg/mL and sorbitol 70 % solution 450 mg/mL

Read all of this leaflet carefully before you start taking TEXA ALLERGY SYRUP because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TEXA ALLERGY SYRUP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

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

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

TEXA ALLERGY SYRUP 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 SYRUP

Do not take TEXA ALLERGY SYRUP:

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

Warnings and precautions

Take special care with TEXA ALLERGY SYRUP:

- TEXA ALLERGY SYRUP is a non-sedating medicine, however some patients may become drowsy after taking the syrup (see Driving and using machinery)
- when taking TEXA ALLERGY SYRUP, alcohol should not be consumed (see Taking TEXA ALLERGY SYRUP 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 SYRUP 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 SYRUP.

Other medicines and TEXA ALLERGY SYRUP

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 SYRUP is not advised.
- As with other antihistamines it is advisable to avoid excessive alcohol consumption.

TEXA ALLERGY SYRUP with food, drink and alcohol

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

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding your baby or 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 this medicine.

Do not use TEXA ALLERGY SYRUP if you are pregnant, planning to become pregnant or you are breastfeeding your baby (see Do not take TEXA ALLERGY SYRUP).

Driving and using machines

TEXA ALLERGY SYRUP can cause drowsiness.

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

Important information about some of the ingredients of TEXA ALLERGY SYRUP:

This medicine contains 450 mg sorbitol in each mL. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with

hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

TEXA ALLERGY SYRUP contains the preservatives methyl parahydroxybenzoate 0,135 % m/v and propyl parahydroxybenzoate 0,015 % m/v which may cause allergic reactions (possibly delayed).

TEXA ALLERGY SYRUP contains saccharin sodium.

3. How to use TEXA ALLERGY SYRUP

Do not share medicines prescribed for you with any other person. Always use TEXA ALLERGY SYRUP exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Adults or children 12 years of age or older:

10 mg (10 mL) once daily.

Children 6 to 12 years old:

10 mg (10 mL) daily, either as a single dose or as divided doses of 5 mL in the morning and 5 ml in the evening.

Children age 2 to 6 years:

5 mg (5 mL) daily, as either a single dose or as divided doses of 2,5 mL in the morning and 2,5 ml in the evening.

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

Your doctor will tell you how long your treatment with TEXA ALLERGY SYRUP will last. If you have the impression that the effect of TEXA ALLERGY SYRUP is too strong or too weak, tell your doctor or pharmacist.

If you take more TEXA ALLERGY 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:

- 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 SYRUP

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

If you stop taking TEXA ALLERGY SYRUP

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

4. Possible side effects

TEXA ALLERGY SYRUP can have side effects.

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

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

- 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
- 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
- abnormal physical weakness or lack of energy, a general feeling of discomfort, illness, or unease, fluid retention

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 any 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.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product. By reporting side effects, you can help provide more information on the safety of the product.

5. How to store TEXA ALLERGY SYRUP

Store all medicines out of reach of children.

Store at or below 25 ºC in a dry place.

Keep well closed.

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 SYRUP contains:

The active substance is cetirizine dihydrochloride.

One mL of TEXA ALLERGY SYRUP contains 1 mg cetirizine dihydrochloride.

The other ingredients are:

Acetic acid, banana flavour, glycerine, methyl parahydroxybenzoate 0,135 % m/v, propylene glycol, propyl parahydroxybenzoate 0,015 % m/v, purified water, saccharin, sodium acetate and sorbitol 70 %.

TEXA ALLERGY SYRUP contains the preservatives methyl parahydroxybenzoate and propyl parahydroxybenzoate. TEXA ALLERGY SYRUP also contains sweeteners (saccharin 1 mg/mL and sorbitol 450 mg/mL) (see Important information about some of the ingredients of TEXA ALLERGY SYRUP).

What TEXA ALLERGY SYRUP looks like and contents of the pack

Clear or almost clear colourless solution with taste and odour of banana.

TEXA ALLERGY SYRUP is available in Type 3 amber glass bottle with a tamper - evident, white coloured closure, contained in a printed outer carton.

Pack sizes: 50 mL*, 100 mL, 150 mL* and 200 mL*.

*Not all pack sizes are marketed.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: +27 21 707 7000

Registration number

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NAMIBIA:

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ZAMBIA:

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MOZAMBIQUE:

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