

PATIENT INFORMATION LEAFLET

TEXA ALLERGY TABLETS

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

TEXA ALLERGY TABLETS tablet

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 pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

1. WHAT TEXA ALLERGY TABLETS CONTAINS

The active substance is cetirizine dihydrochloride.

TEXA ALLERGY TABLETS contains 10 mg cetirizine dihydrochloride.

The other ingredients included in the tablet core are crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and silica colloidal anhydrous.

The film coating contains microcrystalline cellulose, hypromellose, macrogol stearate, titanium dioxide and propylene glycol.

TEXA ALLERGY TABLETS contains sugar (lactose monohydrate 117,0 mg) (see Important information about some of the ingredients of **TEXA ALLERGY TABLETS**).

2. WHAT TEXA ALLERGY TABLETS 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:

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- 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).

3. 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 WHAT TEXA ALLERGY TABLETS CONTAINS)
- 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.

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**.
- **TEXA ALLERGY TABLETS** should not be given to children less than 6 years of age as the tablets may not be suitable for the dosage prescribed.

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Taking TEXA ALLERGY TABLETS with food and drink:

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

Pregnancy and breastfeeding:

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

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking **TEXA ALLERGY TABLETS**.

Driving and using machinery:

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

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

- **TEXA ALLERGY TABLETS** contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **TEXA ALLERGY TABLETS**.
- **TEXA ALLERGY TABLETS** contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with 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.

4. 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

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are not sure.

Adults or children 12 years of age or older:

10 mg (one tablet) once daily.

Children 6 to 12 years old:

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.

If you take more TEXA ALLERGY TABLETS than you should:

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

Symptoms of an 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 the forgotten individual doses.

Effects when treatment with TEXA ALLERGY TABLETS is stopped:

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.

5. POSSIBLE SIDE EFFECTS

TEXA ALLERGY TABLETS can have side effects.

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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 taking **TEXA ALLERGY TABLETS**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **TEXA ALLERGY TABLETS** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat which may cause difficulty in swallowing
- fainting
- severe itching of the skin (with raised lumps), skin rash.

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.

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

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- 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 focussing, 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
- passing less urine than normal
- pain or discomfort when urinating
- wetting the bed, especially by children at night
- weight gain.

Side effects of unknown frequency:

- 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.

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

6. STORING AND DISPOSING OF TEXA ALLERGY TABLETS

Store all medicines out of reach of children.

Store at or below 30 °C 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).

7. PRESENTATION OF TEXA ALLERGY TABLETS

Aluminium/PVC blister packs of 10 or 30 tablets, contained in a printed outer carton.

8. IDENTIFICATION OF TEXA ALLERGY TABLETS

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

9. REGISTRATION NUMBER

A35/5.7.1/0314

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE REGISTRATION HOLDER:

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

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7945, South Africa

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11. DATE OF PUBLICATION:

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NAMIBIA:

NS1 04/5.7.1/1662

ZAMBIA:

P 051/005

MOZAMBIQUE:

2435