**TEXA ALLERGY RANGE**

**SCHEDULING STATUS** S1

**1. NAME OF THE MEDICINE**
**TEXA ALLERGY TABLETS** 10 mg film coated tablets
**TEXA ALLERGY SYRUP** 1 mg/1 mL syrup

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**
TEXA ALLERGY TABLETS: Each film coated tablet contains 10 mg cetirizine dihydrochloride.
TEXA ALLERGY SYRUP: Each 1 mL contains 1 mg cetirizine dihydrochloride.

**Excipients with known effect:**
TEXA ALLERGY TABLETS contains sugar (lactose monohydrate 117,0 mg).
TEXA ALLERGY SYRUP contains sweeteners (saccharin 1 mg/mL and sorbitol 70 % solution 450 mg/mL). Contains no sugar (sucrose).
Contains preservatives (methyl parahydroxybenzoate 0,135 % *m/v* and propyl parahydroxybenzoate 0,015 % *m/v*).
For the full list of excipients, see section 6.1

**3. PHARMACEUTICAL FORM**
Film coated tablets
TEXA ALLERGY TABLETS: Film coated, white to off-white convex, elliptical tablets scored on one side.

Syrup
TEXA ALLERGY SYRUP: Clear or almost clear colourless solution with taste and odour of banana.

**4. CLINICAL PARTICULARS**
**4.1 Therapeutic indications**
TEXA ALLERGY is indicated for symptomatic relief of allergic conditions such as allergic rhinitis, hay fever and allergic skin conditions associated with pruritus, such as urticaria.

**4.2 Posology and method of administration**
**Tablets:**
***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.

**Syrup:**
***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.

**Special populations**
**Elderly:**
No dose adjustment is necessary in healthy elderly patients with normal renal function.

**Dosage in renal impairment:**
In patients with renal impairment, where the creatinine clearance is less than 40 mL/min, the recommended daily dose of cetirizine should be halved.

**Dosage in hepatic impairment:**
In moderate to severe hepatic impairment, half the recommended daily dose should be used.

**Method of administration**
Oral administration.

**Missed dose**
Doctors should advise patients who forget to take TEXA ALLERGY to take a dose as soon as possible and then continue with the normal dose. Patients should not take a double dose to compensate for the missed dose.

**Paediatric population**
TEXA ALLERGY is contraindicated in children under the age of two years, as safety and efficacy have not been demonstrated (see section 4.3).

**4.3 Contraindications**
- hypersensitivity to cetirizine, hydroxyzine, any piperazine derivatives or to any of the ingredients of TEXA ALLERGY
- patients with severe renal impairment at less than 30 mL/min creatinine clearance
- asthma, as it may cause airway obstruction in patients who have previously experienced adverse reactions to antihistamines
- safety in pregnancy and lactation has not been established (see section 4.6)
- children under the age of two years, as safety and efficacy have not been demonstrated.

**4.4 Special warnings and precautions for use**
- TEXA ALLERGY lacks significant sedative effects. Patients should be warned, however, that a small number of individuals may experience sedation
- at therapeutic doses, no clinically significant interactions have been demonstrated with alcohol (for a blood alcohol level of 0,5 g/L). Nevertheless, precaution is recommended if alcohol is taken concomitantly (see section 4.5)
- caution should be taken in patients with predisposition factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as TEXA ALLERGY may increase the risk of urinary retention
- caution in epileptic patients and patients at risk of convulsions is recommended
- the use of the film coated tablet formulation is not recommended in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation
- allergy skin tests are inhibited by TEXA ALLERGY and a wash-out period (of 3 days) is required before performing them
- methyl parahydroxybenzoate and propyl parahydroxybenzoate as contained in TEXA ALLERGY SYRUP may cause allergic reactions (possibly delayed)
- elderly patients are more susceptible to many of the adverse effects of TEXA ALLERGY
- pruritus and/or urticaria may occur when TEXA ALLERGY is stopped, even if those symptoms were not present before treatment initiation. The symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

**Information on excipients of TEXA ALLERGY TABLETS and SYRUP:**
TEXA ALLERGY TABLETS contain lactose monohydrate.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

TEXA ALLERGY SYRUP contains sorbitol.
The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.
The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.
Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

TEXA ALLERGY SYRUP contains saccharin.

**4.5 Interaction with other medicines and other forms of interaction**
Concomitant use of alcohol and other sedating medicines should be avoided.

Due to pharmacokinetic, pharmacodynamic and tolerance profile of cetirizine, no interactions are expected with this antihistamine. Actually, neither pharmacodynamic nor significant pharmacokinetic interaction was reported in drug-drug interactions studies performed, notably with pseudoephedrine or theophylline (400 mg/day).

There is no evidence of an interaction between cetirizine and cimetidine, ketoconazole, erythromycin, azithromycin, diazepam, glipizide and pseudoephedrine.

The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased.

**Alcohol and other Central Nervous System (CNS) depressants:**
In sensitive patients, the concurrent use of alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance, although cetirizine, as in TEXA ALLERGY, does not potentiate the effect of alcohol (see section 4.4).

**4.6 Fertility, pregnancy and lactation**
Safety and efficacy in pregnancy and lactation have not been established (see section 4.3).

**Breastfeeding**
Caution should be exercised when prescribing TEXA ALLERGY to lactating women. Cetirizine is excreted in human breast milk at concentrations representing 25 % to 90 % of those measured in plasma, depending on sampling time after administration.

**Fertility**
Limited data is available on human fertility but no safety concern has been identified.
Animal data show no safety concern for human reproduction.

**4.7 Effects on ability to drive and use machines:**
TEXA ALLERGY can lead to drowsiness and patients should be aware how they react to TEXA ALLERGY and exercise caution before driving, operating hazardous machinery or performing hazardous tasks.

**4.8 Undesirable effects**
**b. Tabulated summary of adverse reactions**

| System Organ Class | Frequency | Side effects |
|---|---|---|
| **Blood and lymphatic system disorders** | *Less frequent* | Thrombocytopenia, leucopoenia, haemolytic anaemia, agranulocytosis |
| **Immune system disorders** | *Less frequent* | Urticaria, skin rash, pruritus, angioedema, hypersensitivity reactions, anaphylaxis |
| **Metabolism and nutrition disorders** | *Frequency unknown* | Increased appetite |
| **Psychiatric disorders** | *Less frequent* | Somnolence, depression, confusion, agitation, aggression, hallucinations, insomnia |
| | *Frequency unknown* | Suicidal ideation, nightmares |
| **Nervous system disorders** | *Less frequent* | Drowsiness, fatigue, malaise, asthenia, tics |
| | *Frequency unknown* | Headaches, dizziness, anxiety, nervousness, paraesthesia, convulsions, movement disorders, dysgeusia, syncope, tremor, dystonia, dyskinesia, amnesia, memory impairment |
| **Eye disorders** | *Less frequent* | Accommodation disorder, blurred vision, oculogyration |
| **Ear and labyrinth disorders** | *Less frequent* | Tinnitus, vertigo |
| **Cardiac disorders** | *Less frequent* | Palpitations, dysrhythmias, tachycardia |
| **Vascular disorders** | *Less frequent* | Hypotension |
| **Respiratory, thoracic and mediastinal disorders** | *Frequent* | Pharyngitis, rhinitis |
| | *Less frequent* | Thickening of mucous, bronchospasm |
| **Gastrointestinal disorders** | *Less frequent* | Nausea, gastrointestinal discomfort, diarrhoea, constipation, dry mouth |
| **Hepatobiliary disorders** | *Less frequent* | Hepatic function abnormal (increased transaminases, alkaline phosphatase, γ-GT and bilirubin), jaundice |
| | *Frequency unknown* | Hepatitis |
| **Skin and subcutaneous tissue disorders** | *Less frequent* | Pruritus, rash, urticaria, fixed drug eruption, photosensitivity, hair loss, sweating |
| | *Frequency unknown* | Acute generalised exanthematous pustulosis |
| **Musculoskeletal, connective tissue and bone disorders** | *Less frequent* | Myalgia |
| | *Frequency unknown* | Arthralgia |
| **Renal and urinary disorders** | *Less frequent* | Dysuria, enuresis, urinary retention |
| **General disorders and administration site conditions** | *Less frequent* | Asthenia, malaise, oedema |
| **Investigations** | *Less frequent* | Weight increased |

**c. Description of selected adverse reactions**
**Skin reactions occurring after discontinuation of TEXA ALLERGY:**
After discontinuation of TEXA ALLERGY, pruritus (intense itching) and/or urticaria have been reported (see section 4.4).

*Reporting of suspected adverse reactions*
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions 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.

**4.9 Overdose**
**Signs and symptoms:**
Symptoms observed after an overdose of cetirizine, as in TEXA ALLERGY, are mainly associated with CNS effects or with effects that could suggest an anticholinergic effect.
Drowsiness is an expected symptom of overdosage. Overdosage may produce agitation, confusion, diarrhoea, dizziness, headache, malaise, mydriasis, restlessness, sedation, somnolence, stupor, pruritus, rash, urinary retention, fatigue, tremor and tachycardia.

Management of overdose:
There is no specific antidote. Cetirizine is not effectively removed by dialysis. Further treatment is symptomatic and supportive.

**5. PHARMACOLOGICAL PROPERTIES**
**5.1 Pharmacodynamic properties**
Pharmacotherapeutic group: Piperazine derivatives
ATC code: R06AE07
Pharmacological classification: A 5.7.1 Antihistaminics.

Mechanism of action
Cetirizine, a metabolite of hydroxyzine, is a selective antagonist of peripheral H1-receptors. *In vitro* receptor binding studies have shown no measurable affinity for other than H1-receptors.

**5.2 Pharmacokinetic properties**
**Absorption:**
Cetirizine is well absorbed from the gastrointestinal tract and peak plasma concentrations of 300 ng/mL are reached within 1 hour after oral administration. The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased. The extent of bioavailability is similar when cetirizine is given as solutions or tablets.
No accumulation is observed for cetirizine following daily doses of 10 mg for 10 days. The distribution of pharmacokinetic parameters such as peak plasma concentration ($C_{max}$) and area under curve (AUC), is unimodal.

**Distribution:**
The apparent volume of distribution is 0,50 L/kg. A high proportion of cetirizine is bound to human plasma proteins (93 ± 0,3 %). Cetirizine does not modify the protein binding of warfarin.

**Biotransformation:**
Cetirizine does not undergo extensive first-pass metabolism.

**Elimination:**
The terminal half-life in adults is approximately 10 hours; in children aged 6 to 12 years, 6 hours; in children aged 2 to 6 years, 5 hours. Cetirizine is eliminated faster in children, and slower in patients with hepatic or renal impairment (creatinine clearance < 40 mL/min), with a resultant increase in half-life and decrease in clearance. The cumulative urinary excretion represents about two thirds of the dose given in both adults and children.

**Linearity/non-linearity:**
Pharmacokinetics are linear over the range of 5 to 60 mg, with plasma concentrations increasing proportionately with increasing doses.

**Pharmacokinetics in special patient groups**
***Elderly:***
Following a single 10 mg oral dose in elderly patients, half-life increases by about 50 % and clearance decreases by 40 % compared to younger patients. The decrease in cetirizine clearance in these elderly patients appears to be related to their decreased renal function.

***Renally impaired patients:***
The pharmacokinetics of cetirizine are similar in patients with mild impairment (creatinine clearance higher than 40 mL/min) and patients with normal renal function. Patients with moderate renal impairment have a 3-fold increase in half-life and 70 % decrease in clearance compared to patients with normal renal function.
Patients on haemodialysis (creatinine clearance less than 7 mL/min) given a single oral 10 mg dose of cetirizine have a 3-fold increase in half-life and a 70 % decrease in clearance compared to patients with normal renal function. Cetirizine is poorly cleared by haemodialysis. Dosing adjustment is necessary in patients with moderate or severe renal impairment (see section 4.2).

***Hepatically impaired patients:***
Patients with chronic liver diseases (hepatocellular, cholestatic and biliary cirrhosis) given 10 or 20 mg of cetirizine as a single dose have a 50 % increase in half-life along with a 40 % decrease in clearance compared to healthy patients.
Dosing adjustment is only necessary in hepatically impaired patients if concomitant renal impairment is present.

**Paediatric population**
***Children, infants and toddlers:***
The terminal half-life in adults is approximately 10 hours; in children aged 6 to 12 years, 6 hours; in children aged 2 to 6 years, 5 hours. This is consistent with the urinary excretion half-life of the medicine.
In infants and toddlers aged 6 to 24 months, it is reduced to 3,1 hours.

**5.3 Preclinical safety data**
Not applicable.

**6. PHARMACEUTICAL PARTICULARS**
**6.1 List of excipients**
**Tablet cores:**
Crospovidone
Lactose monohydrate
Magnesium stearate
Microcrystalline cellulose
Silica colloidal anhydrous.

**Tablet film coating:**
Hypromellose
Macrogol stearate
Microcrystalline cellulose
Titanium dioxide
Propylene glycol.

**Syrup:**
Acetic acid
Banana flavour
Glycerine
Methyl parahydroxybenzoate
Propylene glycol
Propyl parahydroxybenzoate
Purified water
Saccharin
Sodium acetate
Sorbitol 70 %.

**6.2 Incompatibilities**
Not applicable.

**6.3 Shelf life**
TEXA ALLERGY TABLETS: 36 months
TEXA ALLERGY SYRUP: 36 months

**6.4 Special precautions for storage**
TEXA ALLERGY TABLETS: Store at or below 25 ºC in a dry place.
Do not remove the tablets from the blister packs until required for use.
Keep blisters in carton until required for use.
TEXA ALLERGY SYRUP: Store at or below 25 ºC in a dry place.
Keep well closed.

**6.5 Nature and contents of container**
TEXA ALLERGY TABLETS: Aluminium/PVC blister packs of 10, 30 or 500 tablets, contained in a printed outer carton.

TEXA ALLERGY SYRUP: 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.

**6.6 Special precautions for disposal**
No special precautions.

**7. HOLDER OF THE CERTIFICATE OF REGISTRATION**
Pharma Dynamics (Pty) Ltd
1st Floor, Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa

**8. REGISTRATION NUMBER(S)**
TEXA ALLERGY TABLETS: A35/5.7.1/0314
TEXA ALLERGY SYRUP: A41/5.7.1/0086

**9. DATE OF FIRST AUTHORISATION**
TEXA ALLERGY TABLETS: 15 November 2002
TEXA ALLERGY SYRUP: 08 February 2008

**10. DATE OF REVISION OF THE TEXT**
30 November 2022

**NAMIBIA:**
TEXA ALLERGY TABLETS: NS1 04/5.7.1/1662
TEXA ALLERGY SYRUP: NS1 10/5.7.1/0332

**ZAMBIA:**
TEXA ALLERGY TABLETS: P 051/005
TEXA ALLERGY SYRUP: P 051/004

**MOZAMBIQUE:**
TEXA ALLERGY TABLETS: 2435
TEXA ALLERGY SYRUP: 2485

**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 1 mg/mL and sorbitol 70 % solution 450 mg/mL**

**Read all of this leaflet carefully 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 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.

**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.
By reporting side effects, you can help provide more information on the safety of TEXA ALLERGY SYRUP. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure 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**
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**NAMIBIA:**
NS1 10/5.7.1/0332

**ZAMBIA:**
P 051/004

**MOZAMBIQUE:**
2485



**PASIËNTINLIGTINGSBLAD**

**TEXA ALLERGY SYRUP**

**SKEDULERINGSTATUS** S1

**TEXA ALLERGY SYRUP 1 mg per mL**
**Setirisiendihidrochloried**
**TEXA ALLERGY SYRUP bevat geen suiker nie (sukrose)**
**Bevat versoeter: sakkarien 1 mg/mL en sorbitol- 70 % oplossing 450 mg/mL**

**Lees hierdie hele inligtingsblad deeglik deur, aangesien dit belangrike inligting vir u bevat**
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige, of ander gesondheidsorgverskaffer.
- TEXA ALLERGY SYRUP is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

**Inhoud van hierdie inligtingsblad**

1. Wat TEXA ALLERGY SYRUP is en waarvoor dit gebruik word
2. Wat u nodig het om te weet, voordat u TEXA ALLERGY SYRUP gebruik
3. Hoe om TEXA ALLERGY SYRUP te neem
4. Moontlike newe-effekte
5. Hoe om TEXA ALLERGY SYRUP te bewaar
6. Verpakkingsinhoud en ander inligting


**1. Wat TEXA ALLERGY SYRUP is en waarvoor dit gebruik word**
TEXA ALLERGY SYRUP behoort aan 'n groep medisyne wat langwerkende, nie-sederende antihistamiene genoem word.

TEXA ALLERGY SYRUP word gebruik vir die verligting van allergiese toestande soos:
- allergiese rinitis (allergieverwante toe, of loopneus, genies) en hooikoors
- allegiese velreaksies soos urtikarie (uitslag van ronde, rooi swelsels op die vel, wat intens jeuk, somtyds met gevaarlike swelling, wat veroorsaak word deur 'n allergiese reaksie).

**2. Wat u nodig het om te weet, voordat u TEXA ALLERGY SYRUP gebruik**
**Moet nie TEXA ALLERGY SYRUP neem:**
- indien u hipersensitief (allergies) is vir setirisien, hidroksisien, piperasien, of vir enige ander antihistamiene, of vir enige van die bestanddele van TEXA ALLERGY SYRUP nie (kyk afdeling 6)
- indien u aan erge niersiekte ly nie
- indien u aan asma ly en voorheen newe-effekte met antihistamiene ervaar het nie
- indien u swanger is of u baba borsvoed nie (kyk Swangerskap en borsvoeding)
- TEXA ALLERGY SYRUP moet nie aan kinders jonger as twee jaar toegedien word nie, aangesien die veiligheid en doeltreffendheid nog nie nagevors is nie.

**Waarskuwings en voorsorgmaatreëls**
**Neem spesiale sorg met TEXA ALLERGY SYRUP:**
- TEXA ALLERGY SYRUP is 'n nie-sederende medisyne. Sommige pasiënte mag egter lomerig word, nadat die stroop geneem is (kyk Bestuur en die hantering van masjinerie)
- alkoholverbruik moet vermy word, terwyl TEXA ALLERGY SYRUP geneem word (kyk TEXA ALLERGY SYRUP saam met kos en drinkgoed)
- indien u aan enige toestand, wat mag lei tot unrienretensie, ly (vind dit moeilik om u blaas te ledig)
- indien u 'n epileptiese pasiënt is (stuipe ervaar), of u 'n pasiënt met 'n risiko vir konvulsies, is
- indien u vir 'n allergietoets geskeduleer is, moet u die gebruik van TEXA ALLERGY SYRUP vir ten minste 3 dae voor die toets staak, aangesien dit die allergie-toetsresultate mag beïnvloed
- indien u bejaard is, is u meer geneig om newe-effekte met TEXA ALLERGY SYRUP te ervaar.

**Ander medisyne en TEXA ALLERGY SYRUP**
Vertel altyd u gesondheidsorgverskaffer, indien u enige ander medisyne neem. (Dit sluit aanvullende, of tradisionele medisyne in).
- Die gebruik van ander medisyne, wat u lomerig maak (sedeermiddels, kalmeermiddels, of sterk pynstillers) saam met TEXA ALLERGY SYRUP, word nie aanbeveel nie.
- Soos met ander antihistamiene, moet uitermatige alkoholverbruik, vermy word.

**TEXA ALLERGY SYRUP saam met kos, drinkgoed en alkohol**
TEXA ALLERGY SYRUP kan saam met, of sonder maaltye geneem word. Alkohol moet vermy word.

**Swangerskap, borsvoeding en fertiliteit**
Indien u swanger is of u baba borsvoed vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies, voordat hierdie medisyne gebruik word.

Moet nie TEXA ALLERGY SYRUP gebruik indien u swanger is, swangerskap beplan, of u baba borsvoed nie (kyk Moet nie TEXA ALLERGY SYRUP neem).

**Bestuur en die hantering van masjiene**
TEXA ALLERGY SYRUP kan lomerigheid veroorsaak.
Dit is nie altyd moontlik om te voorspel tot watter mate TEXA ALLERGY SYRUP met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle bewus hoe TEXA ALLERGY SYRUP hulle aantas nie.

**Belangrike inligting omtrent sommige van die bestanddele van TEXA ALLERGY SYRUP:**
Hierdie medisyne bevat 450 mg sorbitol per mL. Sorbitol is 'n bron van fruktose. Indien u dokter u vertel het dat u (of u kind) 'n onverdraagsaamheid teenoor sekere suikers het, of indien u gediagnoseer is met oorerflike fruktose-onverdraagsaamheid (OFO), 'n skaars genetiese toestand wat veroorsaak dat iemand nie fruktose kan afbreek nie, moet u u dokter kontak voordat u hierdie medisyne gebruik.
Sorbitol mag spysverteringskanaal-ongemak en 'n matig lakserende effek veroorsaak.
TEXA ALLERGY SYRUP bevat die preserveermiddels metielparahidroksiebensoaat 0,135 % *m/v* en propielparahidroksiebensoaat 0,015 % *m/v*, wat allergiese reaksies (moontlik vertraag) mag veroorsaak.

TEXA ALLERGY SYRUP bevat sakkarien.

**3. Hoe om TEXA ALLERGY SYRUP te neem**
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem TEXA ALLERGY SYRUP altyd presies soos deur u dokter aanbeveel word. U moet u dokter, of apteker raadpleeg, indien u onseker is.

***Volwassenes, of kinders 12 jaar oud, of ouer:***
10 mg (10 mL) een keer daagliks.

***Kinders 6 tot 12 jaar oud:***
10 mg (10 mL) daagliks, of as 'n enkeldosis, of as verdeelde doserings van 5 mL in die oggend en 5 mL saans.

***Kinders 2 tot 6 jaar oud:***
5 mg (5 mL) daagliks, of as 'n enkeldosis, of as 'n verdeelde dosering van 2,5 mL in die oggend en 2,5 mL saans.

Indien u 'n nier-, of lewerversteuring het, moet u 5 mg (5 mL) een keer daagliks neem.

U dokter sal u vertel vir hoe lank u behandeling met TEXA ALLERGY SYRUP sal duur. Indien u onder die indruk is dat die effek van TEXA ALLERGY SYRUP té sterk, of té swak is, vertel u dokter of apteker.

**Indien u meer TEXA ALLERGY SYRUP neem as wat u behoort**
In die geval van oordosering, raadpleeg u dokter, of apteker. Indien beide nie beskikbaar is nie, kontak u naaste hospitaal, of gifbeheersentrum.

Simptome van 'n oordosering, mag die volgende insluit:
- verwarring, diarree, duiseligheid, hoofpyn, algemene gevoel van ongesteldheid, verwyde pupille, rusteloosheid, lomerigheid, verdwaasde toestand, waar dit moeilik is om 'n reaksie te verkry, voel slaperig of moeg, agitasie, veluitslag, urineer minder as wat normaal is vir u, onbeheerbare bewing, of rukkings en 'n vinnige harttempo.

**Indien u vergeet om TEXA ALLERGY SYRUP te neem**
Indien u 'n dosis TEXA ALLERGY SYRUP oorgeslaan het, neem dit so gou as wat u onthou. Indien dit egter amper tyd vir die volgende dosis is, slaan die vergete dosis oor en neem TEXA ALLERGY SYRUP op die volgende geskeduleerde tyd. Moet nie 'n dubbeldosis neem, om op te maak vir die vergete, individuele doserings nie.

**Indien u die gebruik van TEXA ALLERGY SYRUP staak**
Wanneer behandeling met TEXA ALLERGY SYRUP gestaak word, mag u erge gejeuk, of verhewe swelsels op die vel ervaar. Indien dit voorkom, hervat die behandeling met TEXA ALLERGY SYRUP en die newe-effekte behoort te verdwyn.

**4. Moontlike newe-effekte**
TEXA ALLERGY SYRUP kan newe-effekte hê.
Nie alle newe-effekte wat vir TEXA ALLERGY SYRUP aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongewenste effekte ervaar, terwyl u TEXA ALLERGY SYRUP neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van TEXA ALLERGY SYRUP en vertel u dokter onmiddellik, of gaan na die ongevalleafdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk of asemhaling mag bemoeilik
- uitslag of gejeuk
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit het, kon u 'n ernstige allergiese reaksie vir TEXA ALLERGY SYRUP gehad het. U mag dringende mediese aandag, of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalleafdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- aanvalle (stuipe)
- vinnige, of onreëlmatige hartklop
- selfmoordgedagtes (selfmoordneigings)
- vergeling van die vel en oë (geelsug), naarheid, maagpyn, uitputting en koors; tekens van 'n lewerprobleem
- urineer minder as normaal.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- seer keel, loopneus en jeukende neus, genies.

Minder algemene newe-effekte:
- bloedarmoede, met simptome soos uitputting, bleek vel, abnormale bloedtoetsresultate
- bloei en kneus maklik
- voel slaperig of lomerig, depressie, verwarring, aggressie, agitasie, hallusinasies (sien en hoor dinge wat nie daar is nie), onvermoë om te slaap (insomnie)
- spiertrekkings, onbeheerbare bewing, of rukkings
- ongewone moegheid, of swakheid, algemene gevoel van ongesteldheid
- versteurde, of dubbelvisie, oogstremming, moeilike fokus, rol van die oë
- vertigo (voel ongebalanseerd/voel dronk), gelui, of gonsing in die ore (tinnitus)
- lae bloeddruk (lighoofdigheid, duiseligheid)
- 'n hygende klank wanneer u inasem, verdikking van mukus (slym)
- diarree, abdominale pyn, opgeblase, uitermatige winderigheid, naarheid, hardlywigheid, droë mond
- abnormale lewertoetsresultate
- veluitslae, of ander veltoestande, soos jeukerige, of rooi vel, of sensitiwiteit vir lig
- haarverlies, gesweet
- spierpyn
- pyn of ongemak, wanneer u urineer
- bednatmaak, veral snags deur kinders
- gewigstoename
- abnormale fisieke swakheid of energietekort, 'n algemene gevoel van ongemak, siekte of ongemaklikheid, vloeistofretensie.

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms is onbekend:
- verhoging in eetlus
- hoofpyn, duiseligheid
- angstigheid, senuweeagtigheid, geheueverlies
- nagmerries
- tintelende sensasies, brandende, prikkelende gevoel (spelde en naalde), of gevoelloosheid van die vel
- slegte smaak in die mond
- tremors (onbeheerbare bewing)
- uitslag, met blasies wat etter bevat
- gewrigspyn.

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, raadpleeg asseblief u dokter, of apteker.

**Aanmelding van newe-effekte**
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige.
U kan ook newe-effekte by SAHPRA via die aanlynskakel vir ongewenste geneesmiddelreaksie rapporteer: https://www.sahpra.org.za/Publications/Index/8.
Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van TEXA ALLERGY SYRUP in te win. U kan ook 'n epos direk na die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za om veiligheid van die produk te verseker.

**5. Hoe om TEXA ALLERGY SYRUP te bewaar**
Bewaar alle medisyne buite die bereik van kinders.
Bewaar teen of benede 25 ºC in 'n droë plek.
Hou dig toe.
Moet nie gebruik na die vervaldatum wat op die bottel aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in dreine, of rioolstelsels (bv. toilette), weggooi nie.

**6. Verpakkingsinhoud en ander inligting**
**Wat TEXA ALLERGY SYRUP bevat:**
Die aktiewe bestanddeel is setirisiendihidrochloried.
Een mL TEXA ALLERGY SYRUP bevat 1 mg setirisiendihidrochloried.

Die ander bestanddele is:
Asynsuur, gesuiwerde water, gliserien, metielparahidroksiebensoaat 0,135 % *m/v*, natrium-asetaat, piesangeursel, propielparahidroksiebensoaat 0,015 % *m/v*, propileenglikool, sakkarien en sorbitol 70 %.
TEXA ALLERGY SYRUP bevat die preserveermiddels metielparahidroksiebensoaat en propielparahidroksiebensoaat. TEXA ALLERGY SYRUP bevat ook die versoeters (sakkarien 1 mg/mL en sorbitol 450 mg/mL) (kyk Belangrike inligting omtrent sommige van die bestanddele van TEXA ALLERGY SYRUP).

**Hoe TEXA ALLERGY SYRUP lyk en die verpakkingsinhoud**
Helder, of amper helder, kleurlose oplossing, met 'n piesangsmaak en -geur.

TEXA ALLERGY SYRUP is bekikbaar in 'n Tipe 3 amber glasbottel, met 'n peutervrye, wit-kleurige prop, in 'n gedrukte buitenste kartonhouer.
Verpakkingvolumes: 50 mL*, 100 mL, 150 mL* en 200 mL*.
*Nie alle verpakkingsvolumes word bemark nie.

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