PROFESSIONAL INFORMATION

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 contains lactose monohydrate.

Patients with the 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 of 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 Frequency unknown	Somnolence, depression, confusion, agitation, aggression, hallucinations, insomnia Suicidal ideation, nightmares
Nervous system disorders	Less frequent Frequency unknown	Drowsiness, fatigue, malaise, asthenia, tics 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 Less frequent	Pharyngitis, rhinitis Thickening of mucous, bronchospasm

Gastrointestinal disorders	Less frequent	Nausea, gastrointestinal discomfort, diarrhoea, constipation, dry mouth
Hepatobiliary disorders	Less frequent Frequency unknown	Hepatic function abnormal (increased transaminases, alkaline phosphatase, γ-GT and bilirubin), jaundice Hepatitis
Skin and subcutaneous tissue disorders	Less frequent Frequency unknown	Pruritus, rash, urticaria, fixed drug eruption, photosensitivity, hair loss, sweating Acute generalised exanthematous pustulosis
Musculoskeletal, connective tissue and bone disorders	Less frequent Frequency unknown	Myalgia 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. Health care 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.

TEXA ALLERGY SYRUP: Store at or below 25 ºC in a dry place.

6.5 Nature and contents of container

TEXA ALLERGY TABLETS: Aluminium/PVC blister packs of 10,30 tablets or 500, 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, Cape Town

7945, 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

PROFESSIONAL INFORMATION

TEXA ALLERGY RANGE

ZAMBIA:

TEXA ALLERGY TABLETS: P 051/005

TEXA ALLERGY SYRUP: P 051/004

MOZAMBIQUE:

TEXA ALLERGY TABLETS: 2435

TEXA ALLERGY SYRUP: 2485