PROFESSIONAL INFORMATION

TEXA ALLERGY

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

TEXA ALLERGY TABLETS tablet

TEXA ALLERGY SYRUP syrup

COMPOSITION

Active ingredient:

TEXA ALLERGY TABLETS**:** Each film coated tablet contains 10 mg cetirizine dihydrochloride.

Inactive ingredients:

The tablet core contains 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).

Active ingredient:

TEXA ALLERGY SYRUP: Each 1 ml contains 1 mg cetirizine dihydrochloride.

Inactive ingredients:

Acetic acid, banana flavour, glycerol, methyl parahydroxybenzoate, propylene glycol, propyl hydroxybenzoate, purified water, saccharin sodium, sodium acetate, sorbitol 70 %.

TEXA ALLERGY SYRUP contains the preservatives methyl parahydroxybenzoate 0,135 % *m/v* and propyl hydroxybenzoate 0,015 % *m/v.*

TEXA ALLERGY SYRUP contains sweeteners (glycerol 200 mg/ml, saccharin sodium 1 mg/ml and sorbitol 70 % solution 450 mg/ml).

PHARMACOLOGICAL CLASSIFICATION:

A 5.7.1 Antihistaminics.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Cetirizine, a metabolite of hydroxyzine, is a selective antagonist of peripheral H_1-receptors. *In vitro* receptor binding studies have shown no measurable affinity for other than H_1-receptors.

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. Pharmacokinetics are linear over the range of 5 to 60 mg, with plasma concentrations increasing proportionately with increasing doses.

Metabolism:

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.

Special populations

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.

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.

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 DOSAGE AND DIRECTIONS FOR USE).

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.

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.

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 HUMAN REPRODUCTION).
- Children under the age of two years, as safety and efficacy have not been demonstrated.

WARNINGS AND SPECIAL PRECAUTIONS:

- **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 INTERACTIONS).
- 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.

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.

Information on excipients of TEXA ALLERGY TABLETS and SYRUP:

TEXA ALLERGY TABLETS contains lactose. Patients with the rare hereditary conditions of galactose intolerance, e.g. galactosaemia, Lapp lactase deficiency or glucose-galactose malabsorption should not take TEXA ALLERGY TABLETS.

TEXA ALLERGY TABLETS contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

TEXA ALLERGY SYRUP contains sorbitol and may have a laxative effect. Patients with the rare hereditary condition of sorbitol intolerance should not take TEXA ALLERGY SYRUP.

INTERACTIONS:

Concomitant use of alcohol and other sedating medicines should be avoided.

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

HUMAN REPRODUCTION

Safety and efficacy in pregnancy and lactation have not been established (see CONTRAINDICATIONS).

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.

DOSAGE AND DIRECTIONS FOR USE:

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.

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.

SIDE EFFECTS

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
Hepato-biliary 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
Investigations	*Less frequent*	Weight increased

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

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. There is no specific antidote. Cetirizine is not effectively removed by dialysis.

FURTHER TREATMENT IS SYMPTOMATIC AND SUPPORTIVE.

IDENTIFICATION:

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

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

PRESENTATION:

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

TEXA ALLERGY SYRUP: Type 3 amber glass bottle with a tamper evident, white coloured polyethylene closure, contained in a printed outer carton. Pack sizes: 50 ml*, 100 ml, 150 ml* and 200 ml*.

*Not all pack sizes are marketed.

STORAGE INSTRUCTIONS:

TEXA ALLERGY TABLETS: Store at or below 30 ºC in a dry place.

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

KEEP OUT OF REACH OF CHILDREN.

PROFESSIONAL INFORMATION

TEXA ALLERGY

REGISTRATION NUMBERS:

TEXA ALLERGY TABLETS**:** A35/5.7.1/0314

TEXA ALLERGY SYRUP**:** A41/5.7.1/0086

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House,

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7945, South Africa

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

Date of registration:

TEXA ALLERGY TABLETS: 15 November 2002

TEXA ALLERGY SYRUP: 08 February 2008

Date of latest approval:

TEXA ALLERGY TABLETS: 07 January 2020

TEXA ALLERGY SYRUP: 07 January 2020

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