

TEXA SYRUP

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

TEXA SYRUP

COMPOSITION:

Each 1 ml syrup contains 1 mg Cetirizine hydrochloride.

Preservatives: Methyl hydroxybenzoate 0,135% m/v and propyl hydroxybenzoate 0,015 % m/v; does not contain sucrose.

PHARMACOLOGICAL CLASSIFICATION:

A 5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION:

TEXA is a metabolite of hydroxyzine. It is a second-generation reversible, competitive inhibitor of histamine at the histamine-1 (H₁) receptor. Cetirizine competes with histamine for the H₁-receptor site. Cetirizine prevents, but does not reverse, pharmacological responses mediated by histamine, at the H₁ receptor.

Pharmacokinetics:

Cetirizine is well absorbed from the gastro-intestinal tract and peak plasma concentrations are reached within 1 hour after oral administration. Pharmacokinetics are linear, with plasma concentrations increasing proportionately with increasing doses. 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. Cetirizine does not undergo extensive first-pass metabolism. The cumulative urinary excretion represents about two thirds of the dose given in both adults and children.

INDICATIONS:

TEXA is indicated for symptomatic relief of allergic conditions such as allergic rhinitis, and allergic skin conditions such as urticaria.

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients.

Hypersensitivity to hydroxyzine.

Pregnancy, as safety has not been established.

Lactating women, since the active ingredient is excreted in breast-milk.

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

WARNINGS:

Porphyria: Use with caution.

This medicine lacks significant sedative effects.

INTERACTIONS:

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

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

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established (see “**CONTRA-INDICATIONS**”).

DOSAGE AND DIRECTIONS FOR USE:

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) may be given as 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 AND SPECIAL PRECAUTIONS:**Side effects:****Gastro-intestinal system:**

Less Frequent: Nausea, gastro-intestinal discomfort, diarrhoea, constipation, increased appetite and dry mouth have been reported.

Respiratory system:

Less Frequent: Thickening of mucous.

Central Nervous system:

Less Frequent: Drowsiness, fatigue, malaise and asthenia have been reported.

The following have been reported but the frequency is unknown:

Headaches, dizziness, anxiety and nervousness.

Hypersensitivity reactions:

Less Frequent: Urticaria, skin rash, pruritus and angioedema have been reported.

Special precautions:

TEXA lacks significant sedative effects. Patients should be warned, however, that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by simultaneous intake of alcohol or other central nervous system depressants (see “**INTERACTIONS**”).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Drowsiness is an expected symptom of overdosage. Overdosage in children may produce agitation, somnolence, pruritus, rash, urinary retention, fatigue, tremor, and tachycardia.

In the case of massive overdosage, gastric lavage should be performed together with the

usual supportive measures. There is no specific antidote. **TEXA** is not effectively removed by dialysis.

Further treatment is symptomatic and supportive.

IDENTIFICATION:

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

PRESENTATION:

Type 3 amber glass bottle with a tamper evident, white coloured polyethylene closure.

Pack sizes: 50 ml, 100 ml, 150 ml and 200 ml.

STORAGE INSTRUCTIONS:

Store in a cool (below 25°C), dry place.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

41/5.7.1/0086

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

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DATE OF PUBLICATION OF THE PACKAGE INSERT:

22 January 2007

TEXA SYRUP

SKEDULERINGSSTATUS:

S2

EIENDOMSNAAM EN DOSEERVORM:

TEXA SYRUP stroop

SAMESTELLING:

Elke 1 ml stroop bevat 1 mg setirisienhidrochloried.

Preserveermiddels: Metielhidroksibensoaat 0,135% m/v en propielhidroksibensoaat 0,015 % m/v; bevat geen sukrose.

FARMAKOLOGIESE KLASSIFIKASIE:

A 5.7.1 Antihistaminika

FARMAKOLOGIESE WERKING:

TEXA is 'n metaboliet van hidroksisien. Dit is 'n tweede generasie omkeerbare, kompeterende inhibeerder van histamien by die histamien-1 (H₁) reseptor. Setirisien kompeteer met histamien vir die H₁-reseptor bindingsplek. Setirisien voorkom farmakologiese response, wat deur histamien by die H₁ reseptor bemiddel word, maar keer dit nie om nie.

Farmakokinetika:

Setirisien word goed geabsorbeer uit die gastro-intestinale weg en piek plasmakonsentrasies word binne 1 uur na orale toediening bereik. Farmakokinetika is lineêr, met plasmakonsentrasies wat proporsioneel toeneem met toenemende doserings. Die terminale half-leeftyd by volwassenes is ongeveer 10 ure; by kinders van 6 tot 12 jarige ouderdom is dit 6 ure; by kinders van 2 tot 6 jaar is dit 5 ure. Setirisien word vinniger uitgeskei by kinders en stadiger by pasiënte met lewer- of nierontoereikendheid (kreatinienopruiming < 40 ml/min), met 'n gevolglike toename in half-leeftyd en afname in opruiming. Setirisien ondergaan nie uitgebreide eerste deurgang metabolisme nie. Die kumulatiewe urinêre ekskresie verteenwoordig omtrent twee derdes van die dosering gegee aan sowel volwassenes as kinders.

INDIKASIES:

TEXA word aangedui vir simptomatiese verligting van allergiese toestande, soos allergiese rinitis en allergiese veltoestande soos urtikarie.

KONTRA-INDIKASIES:

Hipersensitiwiteit teenoor enige van die bestanddele.

Hipersensitiwiteit teenoor hidroksisien.

Swangerskap, aangesien veiligheid nie bepaal is nie.

Borsvoedende vroue, aangesien die aktiewe bestanddeel uitgeskei word in borsmelk.

Kinders onder die ouderdom van twee jaar, aangesien veiligheid en effektiwiteit nie aangedui is nie.

WAARSKUWINGS:

Porfirie: Gebruik versigtig.

Hierdie medisyne het nie beduidende sederende effekte nie.

INTERAKSIES:

Gelyktydige gebruik van alkohol en ander sederende middels moet vermy word.

Daar is geen bewyse van interaksie tussen setirisien en simetidien, ketokonasool, eritromisien, asitromisien, diasepaam, glipisied en pseudoefedrien nie.

SWANGERSKAP EN LAKTASIE:

Veiligheid tydens swangerskap en laktasie is nie bepaal nie (sien "**KONTRA-INDIKASIES**").

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes of kinders 12 jaar of ouer:

10 mg (10 ml) een keer per dag.

Kinders 6 tot 12 jaar oud:

10 mg (10 ml) daagliks, as 'n enkele dosering of as verdeelde doserings van 5 ml in die oggend en 5 ml saans.

Kinders 2 tot 6 jaar oud:

5 mg (5 ml) kan gegee word as 'n enkele dosering of as verdeelde doserings van 2,5 ml in die oggend en 2,5 ml saans.

Geen aanpassing van die dosering is nodig by gesonde, bejaarde pasiënte met normale nierfunksie nie.

Dosering by Ingekorte Nierfunksie:

By pasiënte met ingekorte nierfunksie, waar die kreatinienopruiming minder as 40 ml/min is, moet die aanbevole daaglikse dosering van setirisien halveer word.

Dosering by Ingekorte Lewerfunksie:

By matige tot erge lewerontoeikendheid, moet die helfte van die aanbevole daaglikse dosering gebruik word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Newe-effekte:

Gastro-intestinale sisteem:

Minder Dikwels: Naarheid, gastro-intestinale ongemak, diarree, hardlywigheid, verhoogde apyt en droë mond is aangemeld.

Respiratoriese sisteem:

Minder Dikwels: Verdikking van mukus.

Sentrale Senuweestelsel:

Minder Dikwels: Lomerigheid, moegheid, malaise en astenie is aangemeld.

Die volgende is aangemeld, maar die frekwensie daarvan is onbekend:

Hoofpyne, lighoofdigheid, angstigheid en senuweeagtigheid.

Hipersensitiwiteitsreaksies:

Minder Dikwels: Urtikarie, veluitslag, pruritus en angio-edeem is aangemeld.

Spesiale voorsorgmaatreëls:

TEXA het nie beduidende sederende effekte nie. Pasiënte moet egter gewaarsku word dat 'n klein aantal individue wel sedering kan ervaar. Om hierdie rede word aanbeveel dat individuele respons bepaal word, voordat bestuur word of gekompliseerde take verrig word. Hierdie effek kan vererger word deur die gelyktydige inname van alkohol of ander sentrale senuweestelselonderdrukkers (sien "**INTERAKSIES**").

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE
BEHANDELING DAARVAN:**

Lomerigheid is 'n simptoem wat verwag kan word met oordosering. Oordosering by kinders kan aanleiding gee tot agitاسie, slaperigheid, pruritus, uitslag, urinêre retensie, uitputting, tremor en tagikardie. In die geval van 'n massiewe oordosis, moet maagspoeling saam met die gewone ondersteunende maatreëls uitgevoer word. Daar is geen spesifieke teenmiddel nie. **TEXA** word nie effektief verwyder deur dialise nie. Verdere behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

Helder of byna helder kleurlose oplossing, met 'n piesangsmaak en -geur.

AANBIEDING:

Tipe 3 amber glas bottel met 'n peuterbestande, wit gekleurde poli-etileen prop.
Verpakkingsgroottes: 50 ml, 100 ml, 150 ml en 200 ml.

BERINGSINSTRUKSIES:

Bewaar in 'n koel (onder 25°C), droë plek.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

41/5.7.1/0086

NAAM EN BESIGHEIDSADRES VAN HOUER VAN DIE REGISTRASIESERTIFIKAAT:

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