

TEXA 10 mg

SCHEDULING STATUS:

S2

PROPRIETARY NAME (AND DOSAGE FORM):

Texa 10 mg (tablets)

COMPOSITION:

Each film-coated tablet contains 10 mg Cetirizine hydrochloride.

PHARMACOLOGICAL CLASSIFICATION:

A: 5.7.1 Antihistaminics.

PHARMACOLOGICAL ACTION:

Cetirizine is a histamine H1 receptor antagonist which does not possess any significant anticholinergic or antiserotonin effects as shown in experimental and clinical pharmacology, which is intended for use as an anti-allergic agent.

The anti-allergic activity of cetirizine is predominantly achieved by its ability to reduce the release of certain mediators (mainly histamine), combined with a selective H1 receptor-blocking action. Eosinophil recruitment induced by antigen-antibody reaction, is also reduced by cetirizine.

Pharmacokinetics

After administration of oral doses of cetirizine peak blood levels are reached within one hour. In adults the terminal half-life is approximately 10 hours, while in children aged 6 to 12 years and in children aged 2 to 6 years, the terminal half-life is 6 hours and 5 hours respectively. The urinary excretion half-life of the medicine confirms these findings. Approximately two thirds of doses given to both adults and children are excreted cumulatively in the urine. In children the apparent plasma clearance is, therefore, higher than that measured in adults. A linear relationship exists between plasma levels and dosage. In humans, cetirizine is primarily bound to plasma proteins.

INDICATIONS:

Allergic reactions, which respond to histamine H1 receptor antagonists:

- Respiratory: Allergic rhinitis, hay fever.
- Cutaneous: Allergic skin conditions associated with pruritus e.g. urticaria.

CONTRA-INDICATIONS:

Known hypersensitivity to the medication or any of its constituents.

As the active ingredient is excreted in breast milk, Texa 10 mg is contra-indicated in breast-feeding women.

The safety in pregnancy has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults, and children 12 years of age or older: One 10 mg tablet daily.

Children 6 to 12 years old: 5 mg (half a tablet) twice daily or 10 mg (one tablet) once daily.

No data are available at present to suggest that dose reduction is required in elderly patients. Reduce dosage to half the usual recommended dose in patients with renal insufficiency.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Texa lacks significant sedative effects; however, a small number of patients may experience sedation. It is therefore recommended that individual responses be determined before recipients drive vehicles or perform other complicated tasks. The simultaneous intake of alcohol or other central nervous system depressants may compound this effect. Mild and transient subjective side-effects such as headache, dizziness, drowsiness, agitation, dry mouth, increased appetite, nervousness and gastro-intestinal discomfort, have occasionally been reported. Hypersensitivity reactions, including skin reactions and angio-oedema, may develop in some individuals.

Antihistamines may suppress the cutaneous histamine response to allergen extracts and should be stopped several days before skin testing.

Interactions: No evidence of interactions in studies with diazepam, and cimetidine have been revealed. It is recommended that excessive alcohol consumption should be avoided.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

If overdosage should occur, patients may exhibit drowsiness. In children, overdosage may cause agitation. Gastric lavage should be performed in cases of massive overdosage. Standard symptomatic and supportive measures should also be taken. No specific antidote has as yet been identified.

IDENTIFICATION:

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

PRESENTATION:

Aluminium/PVC blister packs of 10, 30 or 500 tablets.

STORAGE INSTRUCTIONS:

Store in a cool (below 25°C), dry place.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

35/5.7.1/0314

NAME AND BUSINESS ADDRESS OF APPLICANT:

Pharma Dynamics (Pty) Ltd.
F02 Grapevine House
Steenberg Office Park
WESTLAKE
7945

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

7 January 2002

TEXA 10 mg

SKEDULERINGSTATUS:

S2

EIENDOMSNAAM (EN DOSEERVORM):

Texa 10 mg (tablette)

SAMESTELLING:

Elke filmbedekte tablet bevat 10 mg Setirisienhydrochloried.

FARMAKOLOGIESE KLASSIFIKASIE:

A.: 5.7.1 Antihistamiene.

FARMAKOLOGIESE WERKING:

Setirisien is 'n histamien-H1-reseptorantagonis, wat geen beduidende anticholinergiese of anti-serotonien uitwerkings besit nie, soos aangedui in eksperimentele en kliniese farmakologie, en vir gebruik as 'n anti-allergiese middel bedoel is.

Die anti-allergiese aktiwiteit van setirisien word hoofsaaklik bereik deur dié middel se vermoë om die vrystelling van sekere bemiddelaars (hoofsaaklik histamien) te verminder, wat met 'n selektiewe H1-reseptor-blokkeringsaksie gekombineer is. Eosinofiel-werwing geïnduseer deur antigeen-teenliggaampie reaksie word ook deur setirisien verminder.

Farmakokinetika

Na toediening van orale dosisse setirisien word piek bloedvlakke binne een uur bereik. In volwassenes duur die terminale halfleeftyd ongeveer 10 uur, terwyl in kinders van 6 tot 12 jaar en in kinders van 2 tot 6 jaar, terminale halfleeftyd van 6 uur en 5 uur onderskeidelik, gevind word. Die urinêre uitskeidingshalfleeftyd van die geneesmiddel bevestig hierdie bevindings. Ongeveer twee derdes van dosisse wat vir volwassenes en kinders toegedien word, verskyn kumulatief in die urine. In kinders is die skynbare plasmaopruiming dus hoër as dié wat in volwassenes gemeet word. 'n Liniêre verwantskap bestaan tussen plasmavlakke en dosering. In die mens word setirisien primêr aan plasmaproteïene gebind.

INDIKASIES:

Allergiese reaksies wat op histamien-H1-reseptorantagoniste reageer:

- Respiratories: Allergiese rinitis, hooikoors.
- Vel: Allergiese veltoestande wat met pruritus geassosieer word, bv. urtikarie.

KONTRA-INDIKASIES:

Bekende hipersensitiwiteit teenoor die medikasie of enigeen van sy bestanddele.
Omdat die aktiewe bestanddeel in borsmelk uitgeskei word, is Texa 10 mg teenaangedui in borsvoedende vrouens.
Veiligheid tydens swangerskap is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes, en kinders van 12 jaar en ouer: Een 10 mg tablet per dag.

Kinders van 6 tot 12 jaar: 5 mg (halwe tablet) twee keer per dag of 10 mg (een tablet) een keer per dag.

Geen data is teenswoordig beskikbaar om te suggereer dat dosisvermindering in bejaarde pasiënte benodig word nie. Verminder dosis tot die helfte van die gewone aanbevole dosis in pasiënte met renale ontoereikendheid.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Texa gebrek beduidende kalmerende uitwerkings; 'n klein aantal pasiënte mag egter kalmering ondervind. Dit word dus aanbeveel dat individuele reaksies bepaal word alvorens persone wat die middel neem voertuie bestuur of ander gekompliseerde take uitvoer.

Die gelyktydige inname van alkohol en ander sentrale senuweestelseldepressante mag hierdie uitwerking vererger. Ligte en verbygaande subjektiewe newe-effekte soos hoofpyn, duiseligheid, slaperigheid, agitاسie, droë mond, verhoogde aptyt, senuagtigheid en gastro-intestinale ongemak, is soms aangemeld. Hipersensitiwiteitsreaksies, insluitend velreaksies en angio-edeem, mag in sommige persone ontwikkel.

Antihistamiene mag die kutane histamien response tot allergeen-ekstrakte onderdruk en dit behoort 'n paar dae voor veltoetse gestaak te word.

Interaksies: Geen tekens van interaksies in studies met diasepam en simetidien is waargeneem nie. Dit word aanbeveel dat oormatige alkohol inname vermy word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Indien oordosering sou voorkom, mag pasiënte slaperigheid openbaar. In kinders mag oordosering agitاسie veroorsaak. Maagspoeling moet uitgevoer word in gevalle waar massiewe oordosering plaasgevind het. Standaard simptome en ondersteunende maatreëls behoort ook gebruik te word. Geen spesifieke teenmiddel is tot nou toe geïdentifiseer nie.

IDENTIFIKASIE:

Filmbedekte, wit tot naaswit konvekse, elliptiese tablette wat aan een kant gekeep is.

AANBIEDING:

Aluminium/PVC stolpverpakkings met 10, 30 of 500 tablette.

BERGINGSINSTRUKSIES:

Bewaar op 'n koel (benede 25°C), droë plek.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

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NAAM EN BESIGHEIDSADRES VAN APPLIKANT:

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