PC No.: 8284

**SCHEDULING STATUS**

S2

**PROPRIETARY NAME AND DOSAGE FORM**

**Sensahist**

**COMPOSITION**

Each film-coated tablet contains 10 mg cetirizine dihydrochloride.
Contains sugar: Lactose monohydrate.
Inactive ingredients: Anhydrous calcium hydrogen phosphate, colloidal anhydrous silica, magnesium stearate, maize starch, povidone (K-30), sodium starch glycolate and coating ingredients (hypromellose (E-5), titanium dioxide, propylene glycol and purified talc).

**PHARMACOLOGICAL CLASSIFICATION**

A.5.7.1 Antihistaminics

**PHARMACOLOGICAL ACTION**

**Pharmacodynamic properties:**

Cetirizine dihydrochloride, a metabolite of hydroxyzine, is a histamine $H_1$ receptor antagonist.

**Pharmacokinetic properties:**

Peak blood levels are reached within one hour after oral administration of cetirizine dihydrochloride. Cetirizine dihydrocloride does not undergo extensive first pass metabolism. The terminal half-life is approximately 10 hours in adults, 6 hours in children aged 6 to 12 years and 5 hours in children aged 2 to 6 years. These data are consistent with the urinary excretion half-life of cetirizine. The cumulative urinary excretion represents about two thirds of the dose given in both adults and children. Consequently, the apparent plasma clearance in children is higher than that measured in adults. Plasma levels are linearly related to the dosage given. A high proportion of cetirizine is bound to human plasma proteins. In patients with impaired renal clearance (less than 40 ml/min) and hepatic insufficiency, an increase in half-life and decrease in total clearance occurs.

**INDICATIONS**

Allergic processes responding to a histamine $H_1$ receptor antagonist.

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

**CONTRAINDICATIONS**

History of hypersensitivity to cetirizine dihydrochloride or any of the constituents of Sensahist.
Hypersensitivity to hydroxyzine or any piperazine derivative.
Sensahist is contraindicated in pregnancy and in lactating women (see Pregnancy and Lactation).
Sensahist is contraindicated in children less than 2 years old as the safety has not been established.
Patients with severe renal impairment (creatinine clearance less than 30 ml/min).

**WARNINGS AND SPECIAL PRECAUTIONS**

Sensahist lacks significant sedative effects. However, it is advisable to avoid concomitant use with alcohol or other central nervous system depressants during treatment with Sensahist.

**Effects on ability to drive and use machines:**

Patients should be warned 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 the simultaneous intake of alcohol or other central nervous system depressants.

**Information on other ingredients of Sensahist:**

Sensahist contains lactose; thus patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Sensahist.

**INTERACTIONS**

To date there are no known interactions of Sensahist with other medicines through interactions with medicines metabolised by liver enzymes. Studies with diazepam, glipizide, pseudoephedrine, ketoconazole, azithromycin, erythromycin and cimetidine have revealed no evidence of pharmacokinetic interactions. Concomitant intake of alcohol or other central nervous system depressants may enhance the sedative effects of Sensahist. Allergy skin tests are inhibited by antihistamines such as Sensahist. A washout period of 3 days is recommended before performing such tests.
Ritonavir increases the plasma concentration of racemic cetirizine about 42 %, increases the half-life by 53 % and decreases the clearance by 29 %. The disposition of ritonavir is not altered by concomitant cetirizine administration.

**PREGNANCY AND LACTATION**

Sensahist is contraindicated in pregnancy as safety has not been established (see Contraindications).
Sensahist is contraindicated in lactation since the active ingredient, cetirizine is excreted in breast milk (see Contraindications).

**DOSAGE AND DIRECTIONS FOR USE**

**Adults or children 12 years of age or older:** One 10 mg tablet daily.
**Children 6 to 12 years old:** 10 mg (one tablet) once daily or 5 mg (half a tablet) twice daily.

**Special populations:**

At present there are no data to suggest that the dose needs to be reduced in elderly patients with normal renal function.
In patients with renal insufficiency (creatinine clearance less than 40 ml/min), the dosage should be reduced to half the recommended dose.
Half the recommended daily dose should be used in patients with moderate to severe hepatic impairment.

**SIDE EFFECTS**

Sensahist has the following side effects:
***Blood and the lymphatic system disorder:***
*Less frequent:* Agranulocytosis, leucopenia, haemolytic anaemia, thrombocytopenia, sweating.
***Immune system disorders:***
*Less frequent:* Allergic reactions such as cutaneous reactions, angioedema and anaphylaxis.
***Psychiatric disorders:***
*Less frequent:* Sleep disorders, depression, confusion.
***Nervous system disorders:***
*Frequent:* Tiredness and sleepiness.
*Less frequent:* Headache, dizziness, restlessness, convulsions, drowsiness, fatigue, nervousness, malaise, asthenia and paraethesias.
***Ear and labyrinth disorders:***
*Less frequent:* Tinnitus.
***Cardiac disorders:***
*Less frequent:* Palpitations, ventricular dysrhythmias.
***Vascular disorders:***
*Less frequent:* Hypotension.
***Respiratory, thoracic and mediastinal disorders:***
*Less frequent:* Thickening of mucous.
***Gastrointestinal disorders:***
*Frequent:* Dry mouth, nausea, vomiting, diarrhoea, epigastric pain, increased appetite.
*Less frequent:* Gastric discomfort and gastrointestinal disorders.
***Skin and subcutaneous tissue disorder:***
Less frequent: Hypersensitivity reactions including urticaria, skin rash, pruritus.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**

Drowsiness can be a 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. To date there is no specific antidote. Cetirizine is not effectively removed by dialysis. Further treatment is symptomatic and supportive.

**IDENTIFICATION**

White, capsule shaped film-coated tablets with break line on one side and “M+” embossed on the other side.

**PRESENTATION**

Packaged in transparent PVC film and aluminium foil blister strips of 10 tablets. Strips are packed per unit carton to market as 10’s or 30’s.
Not all pack sizes are marketed at any one time.

**STORAGE INSTRUCTIONS**

Store at or below 25 ºC in original package.
Keep tablets in a dry place. Protect from light.
Keep out of reach of children.

**REGISTRATION NUMBER**

42/5.7.1/0822

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

Oethmaan Biosims (PTY) Ltd
207A Sherwood House
Greenacres Office Park
c/o Victory and Rustenburg Roads
Victory Park, Johannesburg
2195

**DATE OF PUBLICATION OF THE PACKAGE INSERT**

Date of registration: 20 June 2013
Date of revision: --
SE/PI/A

**SKEDULERINGSTATUS**

S2

**EIENDOMSNAAM EN DOSEERVORM**

**Sensahist**

**SAMESTELLING**

Elke filmbedekte tablet bevat 10 mg setirisiendihidrochloried.

Bevat suiker: Laktosemonohidraat.

Onaktiewe bestanddele: Anhidriese kalsiumwaterstoffosfaat, kolloïdale watervrye silika, magnesiumstearaat, mieliestysel, povidoon (K-30), natriumstyselglikolaat en filmbedekkingsbestanddele (hipromellose (E-5), titaniumdioksied, propileenglikol en gesuiwerde talk).

**FARMAKOLOGIESE KLASSIFIKASIE**

A.5.7.1 Antihistaminika

**FARMAKOLOGIESE AKSIE**

**Farmakodinamiese eienskappe:**

Setirisiendihidrochloried, 'n metaboliet van hidroksisien, is 'n histamien $H_1$-reseptorantagonis.

**Farmakokinetiese eienskappe:**

Kruin-bloedvlakke word binne een uur na mondelingse toediening van setirisiendihidrochloried bereik. Setirisiendihidrochloried ondergaan nie uitgebreide eerstedeurgang metabolisme nie. Die terminale halfleeftyd is ongeveer 10 uur in volwassenes, by kinders 6 tot 12 jaar, 6 uur en kinders 2 tot 6 jaar, 5 uur. Hierdie data is in ooreenstemming met die urinêre uitskeidingshalfleeftyd van setirisien. Die kumulatiewe urinêre uitskeiding verteenwoordig ongeveer twee derdes van die dosis wat aan beide volwassenes en kinders toegedien is. Gevolglik is die klaarblyklike plasmaopruiming by kinders hoër as dié gemeet by volwassenes. Plasmavlakke is lineêr verwant aan die dosis wat toegedien is. 'n Groot gedeelte van setirisien is gebonde aan menslike plasmaproteïene. In pasiënte met belemmerde nieropruiming (minder as 40 ml/min) en lewerontoereikendheid, kom 'n verhoging in halfleeftyd en 'n verlaging in totale opruiming voor.

**INDIKASIES**

Allergiese prosesse wat teenoor 'n histamien $H_1$-reseptorantagonis reageer.

- Respiratories: Allergiese rinitis, hooikoors.
- Kutaneus: Allergiese veltoestande verbind met pruritus bv. urtikarie.

**KONTRA-INDIKASIES**

'n Geskiedenis van oorgevoeligheid teenoor setirisiendihidrochloried of enige van die bestanddele van Sensahist.

Hipersensitiwiteit vir hidroksisien of enige piperasienderivate.

Sensahist word teenaangedui tydens swangerskap en by borsvoedende vrouens (Sien Swangerskap en laktasie).

Sensahist word teenaangedui vir kinders jonger as 2 jaar aangesien die veiligheid nog nie bepaal is nie.

Pasiënte met ernstige belemmering van nierfunksie (kreatinienopruiming van minder as 30 ml/min).

**WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**

Sensahist het nie 'n beduidende sederende effek nie. Die gelyktydige gebruik van alkohol of ander sentrale senuweestelseldepressante moet egter vermy word tydens die behandeling met Sensahist.

**Uitwerking op vermoë om motor te bestuur en masjinerie te gebruik:**

Pasiënte moet ingelig word dat sekere individue slaperig kan voel. Dit word dus aanbeveel dat individuele reaksies bepaal moet word alvorens daar bestuur of gekompliseerde take verrig word. Die gelyktydige inname van alkohol of ander sentrale senuweestelseldepressante mag hierdie uitwerking vererger.

**Inligting oor ander bestanddele van Sensahist:**

Sensahist bevat laktose; pasiënte met seldsame oorerflike probleme of galaktose-onverdraagsaamheid, wat ly aan die Lapp-laktasetekort, of wat ly aan wanabsorpsie van glukose-galaktose, moet nie Sensahist gebruik nie.

**INTERAKSIES**

Tans is daar geen bekende interaksies van Sensahist met ander geneesmiddels deur interaksies met geneesmiddels wat deur lewer ensieme gemetaboliseer word nie. Studies met diasepam, glipisied, pseudoefedrien, ketokonasool, asitromisien, eritromisien en simetidien het geen bewyse van farmakokinetiese interaksies gelewer nie. Gelyktydige inname van alkohol en ander sentrale senuweestelseldepressante mag die kalmerende effek van Sensahist verhoog. Antihistamiene soos Sensahist mag allergiese veltoetse inhibeer. Voordat sulke toetse gedoen word, word 'n uitspoeltydperk van 3 dae voorgestel. Ritonavir verhoog die plasmakonsentrasie van rasemiese setirisien met ongeveer 42 %, verhoog die halfleeftyd met 53 % en verlaag die uitskeiding met 29 %. Die gepaardgaande toediening van setirisien verander nie die disposisie van ritonavir nie.

**SWANGERSKAP EN LAKTASIE**

Sensahist word teenaangedui tydens swangerskap aangesien die veiligheid nog nie bepaal is nie (sien Kontra-indikasies).

Sensahist word teenaangedui in borsvoedende moeders, aangesien die aktiewe bestanddeel, setirisien in borsmelk uitgeskei word (sien Kontra-indikasies).

**DOSIS EN GEBRUIKSAANWYSINGS**

**Volwassenes en kinders 12 jaar oud of ouer:** Een 10 mg tablet daagliks.

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

**Spesiale populasies:**

Tans bestaan geen data wat daarop dui dat die dosis verminder moet word by bejaarde pasiënte met normale nierfunksie nie.

By pasiënte met nierontoereikenheid, (kreatinienuitskeiding minder as 40 ml/min) moet die dosis verminder word tot die helfte van die gewone aanbevole dosis.

Helfte van die aanbevole dosis behoort gebruik te word in pasiënte met matige tot erge lewerinkorting.

**NEWE-EFFEKTE**

Sensahist het die volgende newe-effekte:

***Bloed- en limfatiesestelsel versteurings:***

*Minder dikwels:* Agranulositose, leukopenie, hemolitiese anemie, trombositopenie, sweet.

***Immuunstelselversteurings:***

*Minder dikwels:* Allergiese reaksies soos kutaneuse reaksies, angioëdeem en anafilakse.

***Psigiatriese versteurings:***

*Minder dikwels:* Slaapversteurings, depressie, verwarring.

***Senuweestelselversteurings:***

*Dikwels:* Moegheid en slaperigheid.

*Minder dikwels:* Hoofpyn, duiseligheid, rusteloosheid, konvulsies, lomerigheid, vermoeidheid, senuweeagtigheid, ongesteldheid, swakheid en droggevoel.

***Oor- en labirintversteurings:***

*Minder dikwels:* Tinnitus.

***Kardiale versteurings:***

*Minder dikwels:* Palpitasies, ventrikulêre disritmie.

***Vaskulêre versteurings:***

*Minder dikwels:* Hipotensie.

***Respiratoriese, torakale en mediastinale versteurings:***

*Minder dikwels:* Mukusverdikking.

***Gastro-intestinale versteurings:***

*Dikwels:* Droë mond, naarheid, vomering, diarree, epigastriese pyn, verhoogde aptyt.

*Minder dikwels:* Gastriese ongemak en gastro-intestinale versteurings.

***Vel- en subkutane weefselversteurings:***

*Minder dikwels:* Hipersensitiwiteitsreaksies insluitend urtikarie, veluitslag, pruritus.

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

Lomerigheid kan 'n simptoom van oordosering wees. Oordosis by kinders kan agitasie, slaperigheid, pruritus, uitslag, urinêre retensie, vermoeidheid, tremor en tagikardie veroorsaak. In die geval van massiewe oordosering, moet gastriese uitspoeling uitgevoer word, tesame met die gewone ondersteunende maatreëls. Tans is daar geen spesifieke teenmiddel nie. Setirisien word nie effektief deur dialise verwyder nie. Verdere behandeling is simptomaties en ondersteunend.

**IDENTIFIKASIE**

Wit, kapsuulvormige, filmbedekte tablette met 'n breeklyn aan die een kant en met "M+" gebosseleer aan die ander kant.

**AANBIEDING**

Verpak in deursigtige PVC-film met aluminiumfoelie aan die onderkant in stulpstroke van 10 tablette. Stulpstroke word verpak in 'n kartonhouer en bemark as 10 of 30 tablette.

Nie alle verpakkings word altyd gelyktydig bemark nie.

**BEWARINGSINSTRUKSIES**

Bewaar by of benede 25 °C in oorspronlike verpakking.

Hou tablette op 'n droë plek. Beskerm teen lig.

Hou buite bereik van kinders.

**REGISTRASIENOMMER**

42/5.7.1/0822

**NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT**

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**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET**

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