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 ooerflike 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 ritionavir 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
Oethmaan Biosims (EDMS) Bpk
207A Sherwood House
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2195
DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
Datum van registrasie: 20 Junie 2013
Datum van hersiening: --
SE/PI/A

1222197

SCHEDULING STATUS

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
Sensahist (10 mg film-coated tablets)

Read all of this leaflet carefully because it contains important information for you.
Sensahist is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use Sensahist carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share Sensahist with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

1. WHAT SENSAHIST CONTAINS
Each Sensahist tablet contains 10 mg cetirizine dihydrochloride.
Contains sugar: Lactose monohydrate.
The other ingredients are 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).

2. WHAT SENSAHIST IS USED FOR
Sensahist is used to relieve symptoms of allergic reactions such as:
- Allergic rhinitis (allergic inflammation of the nasal pathway), hay fever.
- Allergic skin conditions associated with pruritus (or itch, is an unpleasant sensation that provokes the desire to scratch), e.g. a pale red skin rash condition called urticaria.

3. BEFORE YOU TAKE SENSAHIST
Do not take Sensahist if:
- you have a history of hypersensitivity (allergic) to cetirizine dihydrochloride or any of the constituents of Sensahist.
- you have a hypersensitivity (allergic) to hydroxyzine or piperazine antihistamines.
- you are breastfeeding your baby since the active ingredient is excreted in breast milk.
- you are pregnant as the safety has not been established.
- you have severe kidney problems.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby while taking Sensahist, please consult your doctor, pharmacist or other healthcare professional for advice as safety has not been established.

Driving and using machinery
Some patients being treated with Sensahist may experience drowsiness. If you are intending to drive, engage in potentially hazardous activities or use machines you are therefore advised first to wait and observe your response to the medication.

Important information about some of the ingredients of Sensahist
Sensahist contains lactose; if you have been told by your doctor that you have an intolerance to some sugars you should contact your doctor before taking them.

Taking other medicines with Sensahist
Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicine).
Do not use alcohol or other central nervous system depressants while taking Sensahist as this may increase its effect.

4. HOW TO TAKE SENSAHIST
Do not share medicines prescribed for you with any other person.
Always take Sensahist exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
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.
Not recommended for children under the age of 6.
Patients who have impaired kidney function should take half of the recommended dose.
Patients who have impaired liver function should take half of the recommended dose.

If you take more Sensahist than you should
You may experience drowsiness. Children may experience agitation, somnolence, pruritus, rash, urinary retention, fatigue, tremor and tachycardia.
In the event of an overdose contact your doctor immediately or go to the nearest hospital or poison control center.

If you forget to take Sensahist:
Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS
Sensahist can have side effects.
Not all side effects reported for Sensahist are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Sensahist, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking Sensahist and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Hypersensitivity (allergic) reactions including skin reactions, skin rash or itching.
- Angioedema or swelling that happens just below the surface of the skin, most often around the lips and eyes.

These are all very serious side effects, if you have them, you may have had a serious allergic reaction to Sensahist. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- dry mouth
- asthenia or lack or loss of strength and energy
- changes in the way your heart beats, for example if your heart beats faster
- difficulty breathing.

Tell your doctor if you notice any of the following:
Frequent: diarrhoea, increased appetite, nausea (feeling sick).
Less frequent: headache, dizziness, nervousness, drowsiness, malaise (general bodily weakness or discomfort), fatigue (tiredness), agitation, gastro-intestinal discomfort (stomach pains).
These are all mild effects of Sensahist.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF SENSAHIST
Store at or below 25 ºC in original package.
Keep tablets in a dry place. Protect from light.
Keep out of reach and sight of children.

7. PRESENTATION OF SENSAHIST
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.

8. IDENTIFICATION OF SENSAHIST
White, capsule shaped film-coated tablets with break line on one side and "M+" embossed on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER
42/5.7.1/0822

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Oethmaan Biosims (PTY) Ltd
207A Sherwood House
Greenacres Office Park
c/o Victory and Rustenburg Roads
Victory Park, Johannesburg
2195

11. DATE OF PUBLICATION
Date of registration: 20 June 2013
Date of revision: --

SE/PIL/A

SKEDULERINGSTATUS

S2

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM
Sensahist (10 mg filmbedekte tablette)

Lees die hele voubiljet noukeuring deur, want dit bevat belangrike inligting.
Sensahist is beskikbaar sonder 'n doktersvoorskrif, om 'n ligte toestand te behandel. Dit bly egter belangrik om Sensahist versigtig te gebruik, om die beste resulate te verseker.
- Bêre die voubiljet. Dit kan nodig wees om dit later weer te lees.
- Moet nie Sensahist met ander persone deel nie.
- Indien nodig, vra die apteker vir meer inligting of advies.
- Raadpleeg 'n dokter as die simptome erger word of nie verbeter nie.

1. WAT SENSAHIST BEVAT
Elke Sensahist tablet bevat 10 mg setirisiendihidrochloried.
Bevat suiker: Laktosemonohidraat.
Die ander bestanddele in die tablet is anhidriese kalsiumwaterstoffosfaat, kolloïdale watervrye silika, magnesiumstearaat, mieliestysel, povidoon (K-30), natriumstyselglikolaat en filmbedekkingsbestanddele (hipromellose (E-5), titaniumdioksied, propileenglikol en gesuiwerde talk).

2. WAARVOOR SENSAHIST GEBRUIK WORD
Sensahist word gebruik om verligting te bied vir die simptome van die volgende allergiese toestande soos:
- Allergiese rinitis (allergiese inflammasie van die nasale baan), hooikoors.
- Allergiese veltoestande geassosieer met pruritus (of jeuk, is 'n onaangename sensasie wat die behoefte uitlok om te krap) e.g. urtikarie wat 'n toestand is van 'n bleek, rooi veluitslag.

3. VOORDAT SENSAHIST GEBRUIK WORD
Sensahist moet nie gebruik word as:
- jy 'n geskiedenis het van hipersensitiwiteit (allergies is) vir setirisiendihidrochloried of enige ander bestanddele van Sensahist.
- jy 'n hipersensitiwiteit het (allergies is) vir hidroksisien of piperasienantihistamiene.
- jy jou baba borsvoed, want die aktiewe bestanddeel word in borsmelk vrygestel.
- jy swanger is nie, want die veiligheid is nog nie vasgestel nie.
- jy ernstige nierprobleme het.

Swangerskap en borsvoeding:
Indien jy swanger is of borsvoed terwyl jy Sensahist gebruik, raadpleeg asseblief 'n dokter, apteker of ander professionele verskaffer van gesondheidsorg, aangesien die veiligheid nog nie vasgestel is nie**.**
Bestuur en gebruik van masjinerie
Sommige pasiënte mag lomerigheid ervaar met die gebruik van Sensahist. Jy word aangeraai om eers te wag en seker te maak wat jou reaksie op die medikasie is, voordat jy van voorneme is om te bestuur, betrokke te raak in potensieel gevaarlike aktiwiteite of enige masjinerie gebruik.
Belangrike inligting oor sekere van die bestandele in Sensahist
Sensahist bevat laktose. Kontak jou dokter voordat jy dit neem, indien jou dokter bevestig het dat jy 'n onverdraagsaamheid vir sekere soorte suikers het.
Gebruik van ander medisyne saam met Sensahist:
Onthou om altyd die professionele verskaffer van gesondheidsorg te sê indien ander medisyne gebruik word. (Dit sluit enige aanvullende middels of tradisionele medisyne in).
Moenie alkohol of ander sentraal senuweestelseldepressante saam met Sensahist gebruik nie, want die effek mag versterk word.

4. HOE OM SENSAHIST TE GEBRUIK
Moenie van jou voorskrifmedisyne met enige ander persoon deel nie.
Gebruik Sensahist presies soos jou dokter dit voorskryf het. Vra jou dokter of apteker indien jy onseker is.
Volwassenes of kinders van 12 jaar oud of ouer: Een 10 mg tablet daagliks.
Kinders 6 tot 12 jarige ouderdom: 10 mg (een tablet) eenmaal daagliks of 5 mg (halwe tablet) twee maal daagliks.
Nie aanbeveel vir kinders onder 6 jarige ouderdom nie.
Pasiënte met ingekorte nierfunksie moet die helfte van die aanbevole dosis neem.
Pasiënte met ingekorte lewerfunksie moet die helfte van die aanbevole dosis neem.

As jy meer Sensahist geneem het as die dosis wat aanbeveel is:
Lomerigheid mag ervaar word. Kinders mag rusteloosheid, slaperigheid, pruritis, uitslag, urinêre retensie, moegheid, bewing en tagikardie ervaar.
In geval van oordosis moet 'n dokter dadelik geraadpleeg word, of na die naaste hospitaal of gifbeheersentrum gegaan word.

Indien jy vergeet het om Sensahist te neem:
Moenie 'n dubbele dosis gebruik om te vergoed vir die dosis wat vergeet is nie.

5. MOONTLIKE NEWE-EFFEKTE
Sensahist kan newe-effekte veroorsaak.
Nie alle newe-effekte wat aangemeld is met gebruik van Sensahist word aangedui in die pasiëntinligtingstuk nie. As jou algemene gesondheidstoestand verswak terwyl jy Sensahist gebruik, moet die dokter, apteker of ander professionele verskaffer van gesondheidsorg geraadpleeg word.
Indien enige van die volgende gebeur, staak die gebruik van Sensahist en skakel die dokter dadelik of gaan na die noodeenheid van jou naaste hospitaal:
- Hipersensitiwiteit (allergiese) reaksie insluitende velreaksies, veluitslag of jeuk.
- Angioëdeem of swelling wat net onder die veloppervlak gebeur, gewoonlik om die lippe of oë.

Hierdie is alles ernstige newe-effekte, en indien jy dit ervaar, mag jy 'n ernstige allergiese reaksie teenoor Sensahist hê. Jy mag dringende mediese hulp benodig of gehospitaliseer word.

Kontak jou dokter dadelik of gaan na die noodeenheid van jou naaste hospitaal indien jy die volgende opmerk:
- droë mond
- astenie of gebrek of verlies van krag en energie
- bveranderinge in die manier wat die hart klop, byvoorbeeld wanneer die hart vinniger klop
- moeilike asemhaling.

Kontak jou dokter indien jy die volgende opmerk:
Dikwels: diarree, verhoogde aptyt, naarheid (siek gevoel).
Minder dikwels: hoofpyn, duiseligheid, senuweeagtigheid, lomerigheid, malaise (algehele liggaamlike swakheid of ongemak), moegheid, geirriteerdheid, gastro-intestinale ongemak (maagpyn).
Hierdie is almal ligte newe-effekte van Sensahist.
Indien enige newe-effekte opgemerk word en dit word nie in die pasiëntinligtingstuk genoem nie, moet die geneesheer of apteker in kennis gestel word.

6. HOE OM SENSAHIST TE BÊRE EN WEG TE GOOI
Bewaar by of benede 25 ˚C in die oorspronklike verpakking**.**
Hou tablette in 'n droë plek. Beskerm teen lig.
Hou buite bereik en sig van kinders.

7. AANBIEDING VAN SENSAHIST
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.

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

9. REGISTRASIENOMMER/VERWYSINGSNOMMER
42/5.7.1/0822

10. NAAM EN ADRES VAN REGISTRASIEHOUER
Oethmaan Biosims (EDMS) Bpk
207A Sherwood House
Greenacres Besigheidspark
h/v Victoryweg en Rustenburgweg
Victory Park, Johannesburg
2195

11. DATUM VAN PUBLIKASIE
Datum van registrasie: 20 Junie 2013
Datum van hersiening: **--**

SE/PIL/A

1222197