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
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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 senuweestelselderpressante 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
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