SCHEDULING STATUS: S5

PROPRIETARY NAMES AND DOSAGE FORMS
HALOPERIDOL 1,5 OETHMAAN TABLETS
HALOPERIDOL 5 OETHMAAN TABLETS

COMPOSITION
Each **HALOPERIDOL 1,5 OETHMAAN TABLET** contains: Haloperidol 1,5 mg
Sugar free.

Each **HALOPERIDOL 5 OETHMAAN TABLET** contains: Haloperidol 5 mg
Contains sugar (lactose 81,90 mg and sucrose 20,0 mg)
HALOPERIDOL 1,5 OETHMAAN TABLET:
Ludipress, magnesium stearate.

HALOPERIDOL 5 OETHMAAN TABLET:
Lactose, maize starch, sucrose, colloidal anhydrous silica, magnesium stearate, hexaplate erythrosine supra.

CATEGORY AND CLASS
A 2.6.5 Tranquillisers – Miscellaneous structures

PHARMACOLOGICAL ACTION
Pharmacodynamic Properties
Haloperidol, a butyrophenone, is a neuroleptic agent which produces clinical effects that bear some similarity to those of the phenothiazines. The actions of dopamine in the brain are inhibited and the turnover of dopamine in the brain increased. It reduces psychomotor activity and has anti-emetic actions.
In low doses, operant behaviour is reduced but spinal reflexes are unchanged. Exploratory behaviour is diminished and responses to a variety of stimuli are fewer, slower and smaller.

Pharmacokinetic properties
After oral administration haloperidol is rapidly absorbed with a mean bioavailability of 60 % [42 to 78 % (mean 60 %)]. The variable bioavailability is due to inter-individual differences in gastrointestinal absorption and extent of first-pass hepatic metabolism.
Distribution is rapid to extravascular tissue, haloperidol crosses the blood-brain barrier and is excreted in human breast milk.
Metabolism is by oxidative dealkylation. The elimination half-life is approximately 20 hours, with considerable diurnal variation.

INDICATIONS
Acute and chronic schizophrenia. Mania.
Acute psychoses.

CONTRAINDICATIONS
Hypersensitivity to **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** or any of the ingredients, including excipients.
HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN should not be used alone where depression predominates.
It is contra-indicated in patients with pre-existing central nervous system depression, coma, bone-marrow depression and phaeochromocytoma. It should not be given in conjunction with medicines that might cause leucopenia such as phenylbutazone and thiouracil derivates. The safety in pregnancy and lactation has not been established.

Paediatrics:
It is not recommended for use in children up to three years of age as they are susceptible to extrapyramidal side-effects, especially dystonias.

WARNINGS AND SPECIAL PRECAUTIONS
The risk-benefit profile of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** in patients with epilepsy, Parkinson's and urinary retention should be considered before starting treatment (see "**Special Precautions**").
Geriatric patients tend to develop higher plasma concentrations of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** because of changes in distribution due to decreases in lean body mass, total blood albumin, and often an increase in total body fat composition. These patients usually require lower initial dosage and a more gradual titration of dose.

Special Precautions:
HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN should be used with caution in patients with impaired liver, or history of jaundice, impaired kidney, cardiovascular, cerebrovascular or respiratory function and those with closed-angle glaucoma, Parkinsonism, diabetes mellitus, hypothyroidism, myasthenia gravis, or prostatic hyperplasia.
Caution is required in epileptic patients taking **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** as it lowers the seizure threshold, it should be avoided if possible in untreated epileptics. Debilitated and elderly patients, especially those with dementia, may be more prone to adverse effects of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN**.

If **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** is used in conjunction with other medicines likely to cause postural hypotension an adjustment of dosage may be necessary. Patients should be examined periodically for abnormal skin pigmentation or eye changes and **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** withheld if necessary. Drowsiness is often experienced at the start of treatment with **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** and patients should be advised not to take charge of vehicles or other machinery during this period.
The effects of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** on the vomiting centre may mask symptoms of overdosage of other agents, or of disorders such as gastrointestinal obstruction.
Caution should be taken during administration at extremes of temperature as it may be hazardous since temperature regulation is impaired by **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN**.
Direct exposure to sunlight is not recommended.
Blood counts are advised if the patient develops unexplained infections.
Peripheral anticholinergic effects of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** may also decrease or inhibit salivary flow especially in middle-aged or elderly patients, thus contributing to the development of dental caries, periodontal disease, oral candidiasis, and discomfort. The leucopenic and thrombocytopenic effects of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** may result in increased incidence of microbial infection, delayed healing, gingival bleeding. If leucopenia or thrombocytopenia occurs, dental work should be deferred until blood counts have returned to normal. Patients should be instructed in proper oral hygiene, including proper use of toothbrushes, dental floss and toothpicks.

Effects on the ability to drive and use of machines
Drowsiness is often experienced at the start of treatment with
HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN and patients should be advised not to take charge of vehicles or other machinery during this period.

HALOPERIDOL 5 OETHMAAN contains lactose.
Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose- galactose malabsorption or fructose intolerance should not take **HALOPERIDOL 5 OETHMAAN.** Lactose may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS
Alcohol and central nervous system depressants:
When these agents are taken together with **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN**, it may result in increased central nervous system and respiratory depression and increased hypotensive effects. Alcohol intoxication may also be potentiated. Alcohol may lower the threshold of resistance to neurotoxic side effects.
Antiarrhythmics and halofantrine:
Concomitant administration of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** with antiarrhythmics that prolong the QT-interval may potentiate ventricular arrhythmias.
Guanethidine and other adrenergic neurone blockers:
When given together the antihypertensive action of guanethidine and other adrenergic neurone blockers are reduced.
Anticholinergic agents:
Agents with anticholinergic activity, including tricyclic anti- depressants and the antimuscarinic-antiparkinsonian agents' adverse effects may be potentiated **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN.** The concurrent use of tricyclic antidepressant agents, maprotiline, monoamine oxidase (MAO) inhibitors or trazodone with **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** may prolong and intensify the sedative and anticholinergic effects of either these medicines or of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN**.
Fluoxetine:
The concurrent use of fluoxetine with **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** will potentially increase the risk of central nervous system side effects, particularly extrapyramidal reactions.
Antidiabetic agents:
HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN may cause hyperglycaemia or impair glucose tolerance - the dose of oral hypoglycaemics or insulin may need to be increased in diabetics.
Anticonvulsants including barbiturates:
Concurrent use of these agents with **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** may cause a change in pattern and/or frequency of epileptiform seizures; dosage adjustments of anticonvulsants may be necessary; serum concentration **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** may be significantly reduced by these agents.
Antibacterial agents:
Accelerated **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** clearance occurred in the presence of rifampicin. Black galactorrhoea occurred in patients receiving concomitant therapy with minocycline, perphenazine, amitriptyline hydrochloride and diphenhydramine hydrochloride.
Anticoagulants, coumarin- or indandione-derivatives: Concurrent use with **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** may either increase or decrease anticoagulant activity of these agents; although clinical significance has not been determined, caution is recommended.
Lithium:
Concurrent use of lithium and **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** in high doses may cause irreversible neurological toxicity and brain damage; especially in patients with organic mental syndrome or other central nervous system impairment, extrapyramidal symptoms may be increased by **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** enhancement of dopamine blockade.
Antacids:
The plasma concentrations of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** were significantly lowered after administration of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** with an aluminium hydroxide and magnesium trisilicate antacid.
Metoclopramide:
Concomitant administration may increase the risk of antipsycholic-induced extrapyramidal effects.
Antidyskinetic agents or antihistamines:
Concurrent use with **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** may intensify anticholinergic side- effects. Patients are advised to report gastrointestinal problems since paralytic ileus may occur with concurrent use.
Dosage adjustments may be necessary.
Bromocriptine:
Concurrent use with **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** increases serum prolactin concentrations and interferes with the effects of bromocriptine. Dosage adjustments of bromocriptine may be necessary.
Bupropion:
Concurrent use with **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** may lower the seizure threshold and increase the risk of major motor seizures.
Dopamine:
Concurrent use may antagonise peripheral vasoconstriction produced by high doses of dopamine because of the a-adrenergic blocking action of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN.**
Levodopa or pergolide:
Concurrent use may decrease the therapeutic effects of these agents because of blockades of dopamine receptors by **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN.**
Metaraminol:
HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN decreases, but does not reverse or completely block, the pressor response to metaraminol, because of the a-adrenergic blocking action of haloperidol.
Methyldopa:
Concurrent use with **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** may cause unwanted mental effects such as disorientation and slowed or difficult thought processes.
HUMAN REPRODUCTION
The safety of **HALOPERIDOL 1,5 OETHMAAN and HALOPERIDOL 5 OETHMAAN** in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE
The dosage range may vary between 1 mg and 200 mg per day, depending on the condition and the individual's response to treatment.
Adults: Treatment may be started at 6 to 12 mg daily which may be increased up to 45 mg daily. Up to 200 mg per day has been given in certain cases. When an adequate response is obtained the patient can usually be maintained at a dosage of 1,5 to 3 mg daily. The dosage should be reduced to half of that of the adult dosage in the elderly and debilitated patients.
Children: Maintenance dosage: 0,05 mg per kg body mass per day in 2 divided doses (see "**CONTRA-INDICATIONS**").

SIDE EFFECTS
Nervous system disorders:
A variety of neurological syndromes, involving particularly the extrapyramidal system may occur. Some appear concomitantly with the administration of the medicine and some are late appearing syndromes that occur following prolonged treatment for many months or years. The syndromes and their clinical features are:
Extrapyramidal effects:
Frequent: Akathisia (motor restlessness, not anxiety or agitation), acute dystonic reactions (spasm of muscles of tongue, face, neck and back, may mimic seizures, **not** hysteria) and Parkinsonian syndrome (bradykinesia, rigidity, variable tremor, mask faces and shuffling gait).
Less frequent: Tardive dyskinesia (oral-facial-dyskinesia, widespread choreo-athetosis), neuroleptic malignant syndrome, perioral tremor or "rabbit" syndrome (may be a late variant of Parkinsonism).
Antimuscarinic effects:
Frequent: Dry mouth, constipation, blurred vision, mydriasis, tachycardia, electrocardiographic changes (particularly Q- and T-wave abnormalities) and cardiac arrhythmias.
Less frequent: Difficulty with micturition, hypotension (usually orthostatic).
General nervous system effects:
Less frequent: Delirium, agitation, catatonic-like states, insomnia, drowsiness, dizziness, sweating, convulsions and depression has been reported. Body temperature regulation is impaired and may result in hypo- or hyperthermia depending on the environment.
Cardiac disorders:
The following side effects have been reported but frequencies are unknown:
Less frequent: EEG changes.
Reproductive system and breast disorders:
The following side effects have been reported but frequencies are unknown:
Frequent: Changes in menstrual period (amenorrhoea, galactorrhoea), swelling or soreness in breasts in females and unusual secretion of milk.
Less frequent: Inhibition of ejaculation, impotence, priapism and gynaecomastia.
Metabolism and nutritional disorders:
The following side effects have been reported but frequencies are unknown:
Frequent: Weight gain.
Less frequent: Decreased thirst, loss of weight may occur with high doses.
Skin disorders:
The following side effects have been reported but frequencies are unknown:
Less frequent: A syndrome resembling systemic lupus erythematosus has been reported. Deposition of pigment in the skin and photosensitivity reactions may also occur.
Respiratory disorders:
The following side effects have been reported but frequencies are unknown:
Less frequent: Nasal congestion.
Eye disorders:
The following side effects have been reported but frequencies are unknown:
Less frequent: Deposition of pigment in the eyes; corneal and lens opacities.
Endocrine disorders:
The following side effects have been reported but frequencies are unknown:
Less frequent: Hyperglycaemia and altered glucose tolerance.
Hepato-biliary disorders:
The following side effects have been reported but frequencies are unknown:
Less frequent: Alterations in liver function tests and jaundice (probably of immunological origin).
Blood and lymphatic system disorders:
The following side effects have been reported but frequencies are unknown:
Less frequent: Haemolytic anaemia, aplastic anaemia, thrombocytopenic purpura, and a potentially fatal agranulocytosis have occasionally been reported. Mild leucopenia occurred in some patients with prolonged therapy and high dosage.
Vascular disorders:
The following side effects have been reported but frequencies are unknown:
Less frequent: Oedema.
Gastrointestinal disorders:
The following side effects have been reported but frequencies are unknown:
Less frequent: Gastrointestinal disturbances, nausea and vomiting.
Renal and urinary disorders:
The following side effects have been reported but frequencies are unknown:
Less frequent: Urinary retention.
General disorders:
The following side effects have been reported but frequencies are unknown:
Less frequent: Hypersensitivity reaction (urticaria, exfoliative dermatitis, erythema multiforme, contact sensitivity).
There have been isolated reports of sudden deaths with phenothiazines, including haloperidol. Possible causes include cardiac arrhythmias or aspiration and asphyxia due to suppression of the cough and gag reflexes.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Deaths from overdosage have been reported. Clinical effects of overdosage is usually the exaggeration of adverse effects, i.e. severe breathing difficulty; dizziness; severe drowsiness or comatose state; severe muscle trembling; jerking; stiffness; or uncontrolled movements; severe tiredness or weakness.

Treatment of overdosage:
In severe overdosage the stomach should be emptied by aspiration and lavage, followed by immediate administration of activated charcoal.
Further treatment is symptomatic and supportive.

IDENTIFICATION
HALOPERIDOL 1,5 OETHMAAN: White, biconvex, round tablets 7 mm in diameter.
HALOPERIDOL 5 OETHMAAN: Pink, round, flat tablets with bevelled edge, 8 mm in diameter and scored on one side.

PRESENTATION
HALOPERIDOL 1,5 OETHMAAN:
60 or 100 tablets in securitainers, amber glass containers, sealed aluminium bags or blisters.
500 tablets in securitainers, amber glass containers or blisters.

HALOPERIDOL 5 OETHMAAN:
28, 30, 84 or 100 tablets in securitainers, amber glass containers, sealed aluminium bags or blisters.
500 tablets in securitainers, amber glass containers or blisters.
14 or 56 tablets in securitainers, sealed aluminium bags or blisters.

STORAGE INSTRUCTIONS
Store well closed in a dry place at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
HALOPERIDOL 1,5 OETHMAAN: Q/2.6.5/169
HALOPERIDOL 5 OETHMAAN: Q/2.6.5/170

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Oethmaan Biosims (Pty) Ltd 1st Floor
207A Sherwood House Greenacres Office Park
c/o Victory and Rustenburg Roads
Victory Park Johannesburg 2195

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
Date of registration: 17 June 1983
Date of last approval by Council: 18 April 2008

I822001

Pharmacode Reading Direction
2084

430 mm
175 mm

SKEDULERINGSTATUS: S5

HANDELSNAME EN DOSEERVORMS
HALOPERIDOL 1,5 OETHMAAN-TABLETTE
HALOPERIDOL 5 OETHMAAN-TABLETTE

SAMESTELLING
Elke **HALOPERIDOL 1,5 OETHMAAN-TABLET** bevat 1,5 mg haloperidol.
Suiker-vry

Elke **HALOPERIDOL 5 OETHMAAN-TABLET** bevat 5 mg haloperidol.
Bevat suiker (laktose) 81,90 mg
HALOPERIDOL 1,5 OETHMAAN-TABLET:
Ludipress, magnesiumstearaat.
HALOPERIDOL 5 OETHMAAN-TABLET:
Laktose, mieliestysel, sukrose, kolloïdale anhidriese silika, magnesiumstearaat, heksaplaat-ertrosien-supra.

KATEGORIE EN KLAS
A 2.6.5 Kalmeermiddels – diverse strukture

FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Haloperidol, 'n butirofenon, is 'n neuroleptiese middel wat kliniese effekte soortgelyk aan die van die fenotiasiene uitoefen. Die werking van dopamien in die brein word gerem en die omset van dopamien in die brein word verhoog. Dit verminder psigomotoriese aktiwiteit en het anti-emetiese werking.
Teen lae dosisse word operante gedrag verminder, maar spinale refleksе is onveranderd. Verkennende gedrag word verlaag en reaksies op 'n verskeidenheid stimuli is minder, stadiger en kleiner.

Farmakokinetiese eienskappe
Na orale toediening word haloperidol vinnig geabsorbeer met 'n gemiddelde biobeskikbaarheid van 60% [42 tot 78% (gemiddeld 60%)]. Die veranderlike biobeskikbaarheid is vanweë interindividuele verskille in gastro-intestinale absorpsie en mate van eerstedeurgangmetabolisme in die lewer. Vorsproiding na ekstravaskulêre woefsel is vinnig, haloperidol kruis die bloedbreinskans en word in menslike borsmelk uitgeskei.
Metabolisme is deur oksidatiewe dealkilering. Die eliminasiehalfleeftyd is ongeveer 20 uur, met groot diurnale variasie

INDIKASIES
Akute en/of chroniese skisofrenie Manie
Akute psigose

KONTRA-INDIKASIES
Hipersensitiwiteit teenoor **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5 OETHMAAN of** enige van die bestanddele, waaronder hulpstowwe **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5 OETHMAAN** moet nie alleen gebruik word vir gevalle waar depressie oorheers nie. Dit is teenaangedui vir pasiënte met bestaande onderdrukking van die sentrale senuweestelsel, koma, beenmurgonderdrukking en feochromositoom. Dit moet nie gegee word saam met medisyne word wat leukopenie kan veroorsaak nie, soos fenielbutasoon en tourasieldenivate. Veiligheid en effektiwiteit tydens swangerskap en borsvoeding is nie bepaal nie.

Pediatries:
Dit word nie vir kinders tot drie jaar aanbeweel nie, aangesien hulle vatbaar is vir ekstrapiramidale newe-effekte, veral distonie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS
Die risikovoordeelprofiel van **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5 OETHMAAN** vir pasiënte met epilepsie. Parkinson se siekte en urienretensie moet voor die aanvang van behandeling oorweeg word (kyk "Spesiale voorsorgmaatreëls"). Geriatrese pasiënte is geneig om hoër plasmakonsentrasies van **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5**
OETHMAAN te ontwikkel as gevolg van verandelinge in verspreiding vanweë afname in maer liggaamsmassa, totale bloedalbumien en dikwels 'n toename in totale liggaamsvetsamestelling. Vir hierdie pasiënte is 'n laer aanvangsdosis en 'n meer geleidelike titrasie van die dosis gewoonlik nodig.

Spesiale Voorsorgmaatreëls:
HALOPERIDOL 1,5 OETHMAAN en **HALOPERIDOL 5 OETHMAAN** moet versigtig gebruik word deur pasiënte met verswakte lewer, of 'n geskiedenis van geelsug, swak nier-, kardiovaskulêre, serebrovaskulêre of respiratoriese funksie en diegene met nouhoekgloukoom, Parkinsonisme, diabetes mellitus, hipotireose, myasthenia gravis of prostaathiperplasie. Wees versigtig met epileptiese pasiënte wat **HALOPERIDOL 1,5 OETHMAAN** of **HALOPERIDOL 5 OETHMAAN** drink aangesien dit die drempel vir toevalle verlaag, en dit moet waar moontlik vermy word by onbehandelde epilepsie. Versuwke en bejaarde pasiënte, veral dié met demensie, kan meer geneig wees tot nadelige effekte van **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5 OETHMAAN**.
As **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** gebruik word saam met ander medisyne wat moontlik posturale hipotensie veroorsaak, kan 'n aanpassing in die dosis nodig wees. Pasiënte moet periodiek vir abnormale veldgimentasie of veranderinge in die oë ondersoek word en **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** moet, indien nodig, teruggehou word. Lomerigheid word dikwels aan die begin van behandeling met **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** ondervind en pasiënte moet aangeraai word om nie gedurende hierdie tydperk voertuie te hanteer nie.
Die effekte van **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5 OETHMAAN** op die braaksentrum kan simptome van oordosering van ander middels of van afwykings soos maagdermobstruksie, maskeer.
Wees versigtig tydens toediening by uiterste temperature, aangesien dit gevaarlik kan wees omdat temperatuurregulering deur **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5**
OETHMAAN benadeel word.
Direkte blootstelling aan sonlig word nie aanbeveel nie. Bloedtellings word aangeraai indien die pasiënt onverklaarbare infeksies ontwikkel.
Perifere anticholinergiese effekte van **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5 OETHMAAN** kan ook speeksel/loei verminder of rem veral in middeljarige of ouer pasiënte, wat sodoende bydra tot die ontwikkeling van tandkaries, periodontale siekte, mondelinge kandidiase en ongemak. Die leukopeniese en trombositopeniese effekte van **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5 OETHMAAN** kan tot verhoogde voorkoms van mikrobiese infeksie, vertraagde genesing, gingivale bloeding lei. As leukopenie of trombositopenie voorkom, moet tandheelkundige werk uitgestel word totdat bloedtellings na normaal teruggekeer het. Pasiënte moet onderrig word in behoorlike mondhigiëne, waaronder korrekte gebruik van tandeborsel, tandevlos en tandestokkies.

Effek op die vermoë om motor te bestuur of masjinerie te gebruik
Lomerigheid word dikwels aan die begin van behandeling met
HALOPERIDOL 1,5-OETHMAAN en **HALOPERIDOL 5- OETHMAAN** ondervind en pasiënte moet aangeraai word om nie gedurende hierdie tydperk voertuie te bestuur of masjinerie te hanteer nie.

HALOPERIDOL 5 OETHMAAN bevat laktose.
Pasiënte met die skaars oorerflike toestand van onverdraagbaarheid van galaktose, die Laplandse laktasetekort of wanabsorpsie van glukose/galaktose of met onverdraagbaarheid van fruktose, moet nie **HALOPERIDOL 5 OETHMAAN** drink nie. Laktose mag 'n het effek op die glukemiese beheer in pasiënte wat aan diabetes mellitus lui.

INTERAKSIES
Alkohol en sentralesenustelselonderdrukkers:
As hierdie middels saam met **HALOPERIDOL 1,5 OETHMAAN** of **HALOPERIDOL 5 OETHMAAN** gebruik word, kan dit tot sterker onderdrukking van die sentrale senuweestelsel en asemhaling en verhoogde hipotensiewe effekte lei.
Alkoholvergiftiging kan ook aangebring word. Alkohol kan die drempel vir weerstand teen neuroleptiese newe-effekte verlaag.
Anti-aritmika en halofantrien:
Toediening van **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** saam met anti-aritmika wat die QT-interval verleng, kan ventrikulêre aritmie versterk.
Guanetidien en ander adrenerge neuronblokkers:
Wanneer saam gegee word die anti-hipertensiewe werking van guanetidien en ander adrenergiese neuronblokkers verminder.
Anticholinergiese middels:
Middels met anticholinergiese aktiwiteit, waaronder trisikliese antidepressante en die antimuskarien-antiparkinsonse middels, se nadelige effekte kan deur **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** versterk word.
Die gebruik van trisikliese antidepressante, maprotilien, monoamienoksidasеremmers (MAOR's) of trasodon saam met **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** kan die kalmerende en anticholinergiese effekte van hierdie medisyne of van **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** verleng en versterk.
Fluoksetien:
Die gebruik van fluoksetien saam met **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** sal moontlik die risiko vir newe-effekte op die sentrale senuweestelsel verhoog, veral ekstrapiramidale reaksies.
Antidiabetiese middels:
HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5
OETHMAAN kan hiperglukemie veroorsaak of glukosetoleransie verswak - die dosis van mondelinge hipoglukemika of insulien vir diabete moet dalk by verhoog word.
Antikonvulsante waaronder barbiturate:
Gebruik van hierdie middels saam met **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** kan 'n verandering in patroon en/of frekwensie van epileptiese aanvalle veroorsaak; dosisaanpassings van antikonvulsante mag nodig wees; serumkonsentrasie van **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** kan aansienlik deur hierdie middels verlaag word.
Antibakteriële middels:
Vinniger opruiming van **HALOPERIDOL 1,5-OETHMAAN- en HALOPERIDOL 5 OETHMAAN** het in die teenwoordigheid van rifampisien voorgekom.
Swart galsiktorree het voorgekom in pasiënte wat terselfdertyd behandeling met minosiklien, perfenasien, amitriptilienhidrochlried en difenhidramienhidrochloried ontvang het.
Antikoagulante, kumarien- of indaandioonderivate:
Gebruik saam met **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** kan die antistolleffek van hierdie middels verhoog of verlaag; alhoewel die kliniese belang nie bepaal is nie, word versigtigheid aanbeveel.
Litium:
Gebruik van litium saam met **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** in hoë dosisse kan onomkeerbare neurologiese toksisiteit en breinskade veroorsaak; veral in pasiënte met organiese geestessindroom of ander versteuring van die sentrale senuweestelsel, kan ekstrapiramidale simptome verhoog word deur die versterking van dopamienblokkade deur **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5-OETHMAAN**.
Teensuurmiddels:
Die plasmakonsentrasies van **HALOPERIDOL 1,5 OETHMAAN**
en HALOPERIDOL 5 OETHMAAN is aansienlik verlaag na toediening van **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** saam met 'n teensuurmiddel met aluminiumhidroksied en magnesiumtrisilikaat.
Metoklopramied:
Gelyktydige toediening kan die risiko vir antipsigoties-gelnduseerde ekstrapiramidale effekte verhoog.
Antidiskinetiese middels of antihistamiene:
Gebruik saam met **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** kan anticholinergiese newe- effekte versterk. Pasiënte word aangeraai om gastro-intestinale probleme aan te meld aangesien paralitiese ileus met gelyktydige gebruik kan voorkom. Dit mag nodig wees om die dosis aan te pas
Broomkriptien:
Gebruik saam met **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** verhoog serumprolaktienkonsentrasies en beïnvloed die effekte van broomkriptien. Dit mag nodig wees om die dosis van broomkriptien aan te pas
Bupropioon:
Gebruik saam met **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN** kan die drempel vir toevalle verlaag en die risiko vir groot motoriese aanvalle verhoog.
Dopamien:Gelyktydige gebruik kan perifere vasokonstriksie veroorsaak deur hoë dosisse dopamien as gevolg van die a- adrenergiese blokkeerakse van **HALOPERIDOL 1,5 OETHMAAN en HALOPERIDOL 5 OETHMAAN**.
Levodopa of pergolied:
Gelyktydige gebruik kan die terapeutiese effekte van hierdie middels verminder deur blokkade van dopaminresseptore deur **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5 OETHMAAN.**
Metaraminol:
HALOPERIDOL 1,5 OETHMAAN en **HALOPERIDOL 5 OETHMAAN** verlaag die pressoraksie van metaraminol as gevolg van die a -adrenergiese blokkering van haloperidol, maar keer dit nie om nie of blokkeer dit nie heeltemal nie.
Metieldopa:
Gebruik saam met **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5 OETHMAAN** kan ongewenste geestelike effekte veroorsaak, soos disoriëntasie en vertraagde of moeilike denkprosesse.
MENSLIKE VOORTPLANTING
Die veiligheid van **HALOPERIDOL 1,5 OETHMAAN** en **HALOPERIDOL 5 OETHMAAN** tydens swangerskap en borsvoeding is nie bepaal nie.

DOSIS EN GEBRUIKSAANWYSINGS
Die dosis kan wissel tussen 1 mg en 200 mg per dag, afhangende van die toestand en die individu se reaksie op behandeling.
Volwassenes:
Behandeling kan met 6 tot 12 mg daagliks begin wat tot 45 mg per dag verhoog kan word. Tot en met 200 mg per dag is in sekere gevalle gegee. Wanneer 'n voldoende respons verkry word, kan die pasiënt gewoonlik teen 'n dosis van 1,5 tot 3 mg per dag onderhou word. Die dosis vir bejaardes en verswakte pasiënte moet tot die helfte van die volwasse dosis verlaag word.
Kinders:
Instandhoudingsdosis: 0,05 mg per kg liggaamsmassa per dag in 2 verdeelde dosisse (sien **"KONTRA-INDIKASIES").**

NEWE-EFFEKTE
Versteurings van die senustelsel:
'n Verskeidenheid neurologiese sindrome, wat veral die ekstrapiramidale stelsel behels, mag voorkom. Sommige verskyn saam met die toediening van die medisyne en sommige is sindrome wat laat verskyn kom na langdurige behandeling vir baie maande of jare. Die sindrome en hul kliniese kenmerke is:
Ekstrapiramidale effekte:
Dikwels: Akatisie (motoriese rusteloosheid, nie angs of agitasie nie), akute distoniese reaksies (spasmas van spiere van die tong, gesig, nek en rug, mag soos stuipstrekkings lyk, nie histerie nie) en Parkinsonsindroom (bradikinesie, rigiditeit, veranderlike bewing, maskergesig en skuelfeling.)
Minder dikwels: Laat diskinesie (diskinesie van die mond en gesig, wydverspreide choreo-atetose), neuroleptiese kwaadaardige sindroom, periorale tremor of "konynsindroom" (mag 'n laat variant van Parkinsonisme wees)
Antimuskariene effekte:
Dikwels: Droë mond, hardlywigheid, versteurde visie, midriase, tagikardie, elektrokardiografiese veranderinge (veral Q- en T- golfafwykings) en hartaritmie
Minder dikwels: Probleme met miksturisie, hipotensie (gewoonlik ortostaties).
Effekte op die sentrale senustelsel:
Minder dikwels: Delirium, agitasie, katatoniese toestand, slapeloosheid, lomerigheid, duiseligheid, sweet, stuipstrekkings en depressie is aangemeld. Regulering van liggaamstemperatuur is aangetas en kan tot hipo- of hipertermie lei, afhangende van die omgewing

Versteurings van die hart:
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Minder dikwels: EEG-veranderinge
Versteurings van voortplantingstelsel en borste:
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Dikwels: Veranderinge in menstruasie (amenoree, galaktoree), swelling of pyn in die borste van vroue en ongewone afskeiding van melk
Minder dikwels: Inhibisie van ejakulasie, impotensie, priapisme en ginekomastie
Metabolisme en voedingsversteurings
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Dikwels: Toename in gewig
Minder dikwels: Verminderde dors, gewigsverlies kan by hoë dosisse voorkom
Velversteurings
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Minder dikwels: 'n Sindroom soortgelyk aan sistemiese lupusertematose is aangemeld. Neerslag van pigment in die vel en fotosensitiwiteitsreaksies kan ook voorkom
Respiratoriese versteurings:
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Minder dikwels: Toe neus
Versteurings van die oë:
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Minder dikwels: Neerslag van pigment in die oë; ondeursigtigheid van kornea en lense
Versteurings van endokrienstelsel:
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Minder dikwels: Hiperglisemie en verandering in glukosetoleransie
Hepatobiliêre versteurings:
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Minder dikwels: Veranderinge in lewerfunksietoetse en geelsug (waarskynlik van immunologiese oorsprong)
Versteurings van bloed- en limfstelsel:
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Minder dikwels: Hemolitiese anemie, aplasiese anemie, trombositopeniese purpura en potensieel dodelike agranulositose is soms aangemeld. Ligte leukopenie het met langdurige behandeling en hoë dosisse in sommige pasiënte voorgekom *Vaskulêre versteurings:*
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Minder dikwels: Edeem
Gastro-intestinale versteurings:
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Minder dikwels: Gastro-intestinale versteurings, naarheid en braking
Versteurings van die niere en urien:
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Minder dikwels: Urienretensie
Algemene versteurings:
Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend:
Minder dikwels: Hipersensitiwiteitsreaksie (urtikaria, afskilferende dermatitis, multivorme eritteem en kontaksensitiwiteit)
Daar is geïsoleerde verslae van skielike sterftes met fenotiasiene, insluitend haloperidol. Moontlike oorsake is onder meer hartaritmie of aspirasie en asfiksie as gevolg van onderdrukking van die hoes- en braakrefleksе.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Sterftes van oordosering is aangemeld. Kliniese effekte van oordosering is gewoonlik die verergering van nadelige effekte,
d.w.s. ernstige asemhalingsprobleme; duiseligheid, erge lomerigheid of komatose, erge spierbewings, ruk, stywheid of onbeheerde bewegings, erge moegheid of swakheid.

Behandeling van oordosering
Met erge oordosering moet die maag deur aspirasie en spoeling geledig word, gevolg deur onmiddellike toediening van geaktiveerde houtskool.Verdere behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
HALOPERIDOL 1,5 OETHMAAN: Wit, bikonvekse, ronde tablette van 7 mm in deursnit.
HALOPERIDOL 5 OETHMAAN: Plenk, platt tablette met 'n skuins rand, 8 mm in deursnee met 'n breeklyn op een kant.

AANBIEDING
HALOPERIDOL 1,5 OETHMAAN:
60 of 100 tablette in sekuriteitshouers, amberglashouers, verseëlde aluminiumsakke of stuipstroke.
500 tablette in sekuriteitshouers, amberglashouers of stuipstroke.

HALOPERIDOL 5 OETHMAAN:
28, 30, 84 of 100 tablette in sekuriteitshouers, amberglashouers, verseëlde aluminiumsakke of stuipstroke.500 tablette in sekuriteitshouers, amberglashouers of stuipstroke.
14 of 56 tablette in sekuriteitshouers, verseëlde aluminiumsakke of stuipstroke.

BEWARINGSINSTRUKSIES
Hou dig geslote en berg op 'n droë plek teen of benede 25 °C.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIE NOMMER
HALOPERIDOL 1,5 OETHMAAN: Q/2.6.5/169
HALOPERIDOL 5 OETHMAAN: Q/2.6.5/170

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
Oethmaan Biosims (Edms) Bpk 1[ste]Vloer
207A Sherwood House Greenacres Kantoorpark
h/v Victory- en Rustenburgweg Victory Park
Johannesburg 2195

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Pharmacode Reading Direction
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430 mm

175 mm