PC.NO.8262

SCHEDULING STATUS S3

PROPRIETARY NAME AND DOSAGE FORM
VERAPAMIL 40 OETHMAAN TABLETS
VERAPAMIL 80 OETHMAAN TABLETS
VERAPAMIL 120 OETHMAAN TABLETS

COMPOSITION
Per tablet:
VERAPAMIL 40 OETHMAAN: Verapamil hydrochloride 40 mg
VERAPAMIL 80 OETHMAAN: Verapamil hydrochloride 80 mg
VERAPAMIL 120 OETHMAAN: Verapamil hydrochloride 120 mg
Contains sugar (lactose):
VERAPAMIL 40 OETHMAAN: 45,50 mg
VERAPAMIL 80 OETHMAAN: 91,00 mg
VERAPAMIL 120 OETHMAAN: 135,50 mg
Excipients: Colloidal silicon dioxide, lactose, maize starch, magnesium stearate, povidone K-30, purified talc, sodium starch glycolate

CATEGORY AND CLASS
A 7.1.4 Vasodilators-coronary and other medicines used in angina pectoris

PHARMACOLOGICAL ACTION
Pharmacodynamic Properties
Verapamil is a calcium antagonist which reduces myocardial oxygen consumption in vitro directly by intervening in the energy consuming metabolic processes of the myocardial cell and indirectly by diminishing the peripheral resistance (afterload), it prolongs impulse conduction in the AV-node.

INDICATIONS
Angina pectoris, supraventricular dysrhythmias.

CONTRAINDICATIONS
Cardiogenic shock, acute phase of cardiac infarct, complete atrioventricular block, manifest cardiac insufficiency without preceding digitalization. Special caution should be exercised when the patient has partial atrioventricular block, left bundle branch block, bradycardia or hypertension.
Verapamil hydrochloride should not be given as an injection together with, or to a patient who has recently received a beta-blocking agent.

WARNINGS AND SPECIAL PRECAUTIONS
Intravenous verapamil hydrochloride should be given with care to patients receiving digitalis as complete heart block may be precipitated.

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 VERAPAMIL OETHMAAN. Lactose may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS
During the simultaneous administration of verapamil hydrochloride and medicines with cardio-depressive effect and/or inhibiting effect on atrioventricular conduction (e.g. beta-receptor blockers) the patient should be observed for additive effects.
Verapamil hydrochloride may intensify the blood pressure lowering effect of antihypertensives and this makes it often possible to reduce the dose of the antihypertensive, particularly in patients on long-term treatment with verapamil hydrochloride. Rises in digoxin plasma levels under concomitant administration of verapamil hydrochloride have been reported. However, extensive experience indicates that this possible interaction is of only slight clinical relevance. Physicians should be alert for symptoms of possible digitalis intoxication.

HUMAN REPRODUCTION
Verapamil hydrochloride should not be used during pregnancy.

DOSAGE AND DIRECTIONS FOR USE
VERAPAMIL 40 OETHMAAN tablets: 1 to 2 tablets three times a day
VERAPAMIL 80 OETHMAAN tablets: 1 tablet three times a day
VERAPAMIL 120 OETHMAAN tablets:1 tablet three times a day

SIDE EFFECTS
Nausea, vomiting, constipation, dizziness, flushing, exacerbations of arthritis, increased urination, epigastric pain, burning sensation of the gums, headache, fatigue, palpitations, 1st and 2nd degree AV-block, SA-block, mild tremor, severe facial pain, temporary skin rash and urticaria may occur.
Verapamil hydrochloride inhibits AV conduction and may cause a complete AV-block and even asystole after intravenous injection. Hypotension may occur. Verapamil hydrochloride may precipitate cardiac failure. Allergy has been reported.
In patients with diminished hepatic functions (parenchymal loss/reduced blood supply) the effect of verapamil hydrochloride is intensified and prolonged depending on the severity of the disease due to impaired drug metabolism. In these cases, dosage should be adjusted with special care.
In atrial fibrillation and simultaneous WPW syndrome there is a risk of precipitating ventricular fibrillation.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Severe cardiac depression and hypotension may occur. Treatment is supportive and symptomatic.

IDENTIFICATION
VERAPAMIL 40 OETHMAAN AND VERAPAMIL 80 OETHMAAN:
Round, white, biconvex film-coated tablets.
VERAPAMIL 120 OETHMAAN:
Round, white to off white, biconvex film-coated tablets.

PRESENTATION
VERAPAMIL 40 OETHMAAN: 30, 84 or 100 tablets packed in blisters, securitainers, sealed aluminium bags or amber glass bottles. 500 tablets packed in blisters, securitainers or amber glass bottles.
VERAPAMIL 80 OETHMAAN: 50 or 100 tablets packed in blisters, securitainers, sealed aluminium bags or amber glass bottles. 250 tablets packed in blisters, securitainers or amber glass bottles.
VERAPAMIL 120 OETHMAAN: 50, 100 or 250 tablets packed in blisters, securitainers or amber glass bottles.

STORAGE INSTRUCTIONS
Store at or below 25 °C and protect from light. Keep the container well closed.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER
VERAPAMIL 40 OETHMAAN: Q/7.1.4/161
VERAPAMIL 80 OETHMAAN: Q/7.1.4/162
VERAPAMIL 120 OETHMAAN: S/7.1.4/62

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Oethmaan Biosims (PTY) Ltd
207A Sherwood House
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2195

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
Date of registration:
VERAPAMIL 40 OETHMAAN: 02 February 1983
VERAPAMIL 80 OETHMAAN: 02 February 1983
VERAPAMIL 120 OETHMAAN: 02 July 1987
Date of last approval by Council: 28 August 1984

SKEDULERINGSTATUS S3

EIENDOMSNAAM EN DOSEERVORM
VERAPAMIL 40 OETHMAAN-TABLETTE
VERAPAMIL 80 OETHMAAN-TABLETTE
VERAPAMIL 120 OETHMAAN-TABLETTE

SAMESTELLING
Per tablet:
VERAPAMIL 40 OETHMAAN: 40 mg verapamielhidrochloried
VERAPAMIL 80 OETHMAAN: 80 mg verapamielhidrochloried
VERAPAMIL 120 OETHMAAN: 120 mg verapamielhidrochloried

Bevat suiker (laktose):
VERAPAMIL 40 OETHMAAN: 45,50 mg
VERAPAMIL 80 OETHMAAN: 91,00 mg
VERAPAMIL 120 OETHMAAN: 135,50 mg

Hulpstowwe:
Kolloïdale silikondioksied, laktose, mieliestysel, magnesiumstearaat, povidoon K-30, gesuiwerde talk, natriumstyselglikolaat

KATEGORIE EN KLAS
A 7.1.4 Vasodilatore - hart- en ander medisyne gebruik vir angina pectoris

FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Verapamiel is 'n kalsiumantagonis wat miokardiale suurstofgebruik in vitro direk verminder deur in die energieverbruikende metaboliese prosesse van die miokardiale sel in te meng en indirek deur die perifere weerstand (nabelading) te verminder, dit verleng impulsgeleiding in die AV-knoop.

INDIKASIES
Angina pectoris en supraventrikulêre disritmie.

KONTRA-INDIKASIES
Kardiogene skok, akute fase van hartinfarkt, volledige atrioventrikulêre blok, gemanifesteerde swak hartfunksie sonder voorafgaande behandeling met digitalis. Wees besonder versigtig wanneer die pasiënt gedeeltelike atrioventrikulêre blok, linkerbondeltakblok, bradikardie of hipertensie het. Verapamielhidrochloried moet nie as 'n inspuiting saam met 'n beta-blokker gegee word nie, en ook nie aan 'n pasiënt wat dit onlangs ontvang het nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Intraveneuse verapamielhidrochloried moet versigtig gegee word aan pasiënte wat digitalis kry, aangesien 'n volledige hartblok aangebring kan word.
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 **VERAPAMIL OETHMAAN** drink nie. Laktose mag 'n effek het op die glukemiese beheer van pasiënte wat aan diabetes mellitus lui.

INTERAKSIES
Wanneer verapamielhidrochloried toegedien word saam met middels met 'n onderdrukkende effek op die hart en/of remmende effek op atrioventrikulêre geleiding (bv. beta-reseptorblokkers) moet die pasiënt dopgehou word vir additiewe effekte.
Verapamielhidrochloried kan die bloeddrukverlagende effek van antihipertensiewe middels versterk, en dit maak dit dikwels moontlik om die dosis van die hipertensiewe middel te verminder, veral vir pasiënte met langtermynbehandeling met verapamielhidrochloried. Stygings in plasmavlakke van digoksien onder die toediening van verapamielhidrochloried is ook aangemeld. Uitgebreide ondervinding dui egter daarop dat hierdie moontlike interaksie slegs van geringe kliniese belang is. Dokters moet oplet vir simptome van moontlike digitalisvergiftiging.

MENSLIKE VOORTPLANTING
Verapamielhidrochloried moet nie tydens swangerskap gebruik word nie.

DOSIS EN GEBRUIKSAANWYSINGS
VERAPAMIL 40 OETHMAAN tablette: 1 tot 2 tablette drie keer per dag
VERAPAMIL 80 OETHMAAN tablette: 1 tablet drie keer per dag
VERAPAMIL 120 OETHMAAN tablette: 1 tablet drie keer per dag

NEWE-EFFEKTE
Naarheid, braking, hardlywigheid, duiseligheid, blosing, verergering van artritis, meer dikwelse urinering, epigastriese pyn, brandsensasie van die tandvleis, hoofpyn, moegheid, palpitasies, 1ste- en 2de-graadse AV-blok, SA-blok, ligte tremor, erge pyn in die gesig, tydelike veluitslag en urtikarie kan voorkom. Verapamielhidrochloried rem AV-geleiding en kan na intraveneuse inspuiting 'n volledige AV-blok en selfs asistool veroorsaak. Hipotensie mag voorkom. Verapamielhidrochloried kan hartversaking aanbring. Allergie is aangemeld.In pasiënte met swak lewerfunksie (verlies van parenchiem/swak bloedtoevoer) is die effek van verapamielhidrochloried vanweë stadige metabolisme sterker en langer afhangende van die graad van die siekte. Vir hierdie gevalle moet die dosis versigtig aangepas word. Met atriale fibrillasie saam met die Wolff-Parkinson-Whitesindroom is daar 'n risiko dat ventrikulêre fibrillasie aangebring kan word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Erge onderdrukking van hartfunksie en hipotensie kan voorkom.
Behandeling is ondersteunend en simptomaties.

IDENTIFIKASIE
VERAPAMIL 40 OETHMAAN en VERAPAMIL 80 OETHMAAN:
Ronde, wit, bikonvekse filmbedekte tablette.
VERAPAMIL 120 OETHMAAN:
Ronde, wit tot afwit, bikonvekse filmbedekte tablette.

AANBIEDING
VERAPAMIL 40 OETHMAAN: 30, 84 of 100 tablette in stulppakke, veiligheidshouers, geseëlde aluminiumsakke of bruin glasbottels. 500 tablette in stulppakke, veiligheidshouers of bruin glasbottels.
VERAPAMIL 80 OETHMAAN: 50 of 100 tablette in stulppakke, veiligheidshouers, geseëlde aluminiumsakke of bruin glasbottels. 250 tablette in stulppakke, veiligheidshouers of bruin glasbottels.
VERAPAMIL 120 OETHMAAN: 50, 100 of 250 tablette in stulppakke, veiligheidshouers of bruin glasbottels.

BEWARINGSINSTRUKSIES
Hou dig geslote by of onder 25 °C en beskerm teen lig.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER
VERAPAMIL 40 OETHMAAN: Q/7.1.4/161
VERAPAMIL 80 OETHMAAN: Q/7.1.4/162
VERAPAMIL 120 OETHMAAN: S/7.1.4/62

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
Oethmaan Biosims (EDMS) Bpk
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2195

DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING
Registrasiedatum:
VERAPAMIL 40 OETHMAAN: 02 Februarie 1983
VERAPAMIL 80 OETHMAAN: 02 Februarie 1983
VERAPAMIL 120 OETHMAAN: 02 Julie 1987
Datum van laaste goedkeuring deur raad: 28 Augustus 1984