PACKAGE INSERT

Scheduling status **S3**

Proprietary names (and dosage forms):

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

Pharmacological classification

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

Pharmacological action

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.

Contra-indications

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. Verapamil hydrochloride should not be used during pregnancy. Intravenous verapamil hydrochloride should be given with care to patients receiving digitalis as complete heart block may be precipitated.

Warnings and special precautions

Interactions: During the simultaneous administration of verapamil hydrochloride and medicines with cardio-depressive effect and/or inhibiting effect on atrioventricular conduction (e.g. β-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**.**

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

Keep well-closed, at or below 25 °C and protect from light.

KEEP OUT OF THE REACH OF CHILDREN.

Registration numbers

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.

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