SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

SULPIRIDE 50 OETHMAAN Capsules

COMPOSITION

Each **SULPIRIDE 50 OETHMAAN** Capsule contains: 50 mg Sulpiride.

Excipients: Lactose DC, magnesium stearate , maize starch, purified talc, and gelatine capsules
Contains sugar (lactose): 83 mg

CATEGORY AND CLASS

A 2.6.5 Tranquillisers; Miscellaneous structures

PHARMACOLOGICAL ACTION

Sulpiride is a substituted benzamide with neuroleptic properties.

INDICATIONS

In psychiatry:
Reactive depression, depression associated with psychoses of other origins.
Prophylaxis and treatment of depressive psychoses.
Schizophrenia, particularly with the symptoms of hallucinations, autism, aggressiveness and in the case of withdrawn-inhibited types of schizophrenia.
Acute delirium, acute hallucinatory and confusional states.
Behaviour disorders in all age groups where abnormal aggressive symptoms are in the forefront.
In gastroenterology:
As an adjunct in the treatment of duodenal ulceration.
Other:
In the treatment of vertigo.

CONTRAINDICATIONS

Hypersensitivity to **SULPIRIDE 50 OETHMAAN**, other phenothiazines or any of the ingredients, including excipients. (see COMPOSITION).
SULPIRIDE 50 OETHMAAN is not recommended in hypomanic patients, in the manic or premanic phase of manic-depressive psychosis, or in patients with acute mania. See “Side effects” and “Warnings and special precautions”.

SULPIRIDE 50 OETHMAAN should not be administered to patients with pre-existing central nervous system depression or coma, phaeochromocytoma or bone-marrow suppression and only with caution to patients with hypertension.
SULPIRIDE 50 OETHMAAN is considered to be unsafe in patients with acute porphyria.
The safety in pregnancy and lactation has not been established.

WARNINGS AND SPECIAL PRECAUTIONS

In psychotically suicidal cases, **SULPIRIDE 50 OETHMAAN**, because of its disinhibitory effect, should be administered with care and combined with other forms of psychotherapy. Caution should be exercised when medicines with known extrapyramidal side-effects are combined with **SULPIRIDE 50 OETHMAAN**. Tardive dyskinesia may occur.
SULPIRIDE 50 OETHMAAN should be used with caution in patients with impaired liver, kidney, cardiovascular, cerebrovascular and respiratory function, and in those with closedangle glaucoma, parkinsonism, diabetes mellitus, hypothyroidism, myasthenia gravis or prostatic hypertrophy. Care is required in epileptic patients on anticonvulsant therapy, as the seizure threshold could be lowered. The use of **SULPIRIDE 50 OETHMAAN** should be avoided in untreated epileptics, if possible.
Elderly, especially those with dementia, and debilitated patients may be more prone to adverse effects.
Effects on the vomiting centre may mask the symptoms of overdosage of other agents, or of disorders such as gastrointestinal obstruction.
Administration at extremes of temperature should be avoided since body temperature regulation may be impaired.
Regular eye examinations are advisable for patients receiving long-term therapy.
Avoidance of undue exposure to direct sunlight is recommended. Haematological parameters should also be monitored periodically.
Abrupt withdrawal should be avoided.

Effects on ability to drive and use machines:

The use of this medicine may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Affected patients should not drive or operate machinery.

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 **SULPIRIDE 50 OETHMAAN**. Lactose may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS

Symptoms of central nervous system depression may be enhanced by other medicines with central nervous system depressant properties including, alcohol, general anaesthetics, hypnotics, sedatives and opioid anaesthetics.
Dose adjustments may be necessary when given with other medicines that produce postural hypotension.
The antihypertensive effects of guanethidine and other adrenergic neuron blockers may be reduced.
The adverse effects of other antimuscarinic medicines may be potentiated, including tricyclic antidepressants and the antimuscarinic anti-parkinsonian medicines which may be given to treat extrapyramidal effects.
Concomitant administration of metoclopramide may increase the risk of extrapyramidal effects. Halofantrine, anti-arrhythmics, antihistamines, antimalarial agents and cisapride which prolong the QT interval, may increase the possibility of ventricular arrhythmias.

HUMAN REPRODUCTION

Safety during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

SULPIRIDE 50 OETHMAAN should be given in reduced doses to elderly patients.
In psychiatry:
Adults:
Initial treatment:
100 to 150 mg per day up to 300 mg per day (2 to 6 capsules) in divided doses for common, milder psychiatric conditions of shorter duration and behavioural disorders.
Maintenance treatment: Reduce or increase as necessary.
General: Duration of treatment as necessary; slow decrease in dosages before total withdrawal.
Dosage may be increased to 1 200 to 1 600 mg per day in divided doses, for severe psychiatric disorders.
Children:
An oral dose of 3 to 5 mg per kg body mass.
In gastroenterology:
150 to 300 mg **SULPIRIDE 50 OETHMAAN** (3 to 6 capsules) daily in divided doses.
In vertigo:
150 to 300 mg **SULPIRIDE 50 OETHMAAN** (3 to 6 capsules) daily for 15 to 20 days.

SIDE EFFECTS

Nervous system disorders:
Frequent: Akathisia (restlessness or need to keep moving), acute dystonia, parkinsonismlike syndrome, tardive dyskinesia and dry mouth.
Less frequent: Insomnia, catatonic-like states, EEG changes, convulsions and temperature regulation dysfunction.
SULPIRIDE 50 OETHMAAN may produce sedation, sleep disturbances, overstimulation, agitation, delirium, depression and miosis. **SULPIRIDE 50 OETHMAAN** may lead to extrapyramidal symptoms in high doses. Perioral tremor and neuroleptic malignant syndrome have also been reported.
Respiratory disorders:
Frequent: Nasal congestion has been observed.
Renal and urinary disorders:
Less frequent: Micturition difficulty.
Gastrointestinal disorders:
Frequent: Constipation can occur.
Eye disorders:
Frequent:
Prolonged therapy may lead to deposition of pigment in the eyes. Blurred vision, corneal and lens opacities have been observed.
Less frequent:
Photosensitivity reactions can occur.
Mydriasis has been reported.
Vascular disorders:
Frequent: Hypotension (usually postural) and hypertension were observed.
Cardiac disorders:
Less frequent: Cardiac arrhythmias.
Tachycardia and electrocardiographic changes have occurred.
Skin and subcutaneous disorders:
Less frequent: Systemic lupus erythematosus.
Prolonged therapy may lead to deposition of pigment in the skin.
Hepato-biliary disorders:
Less frequent: Jaundice.
Minor abnormalities in liver function tests may occur.
Endocrine disorders:
The following side effects have been reported, but the frequencies are unknown:
Hyperglycaemia and altered glucose tolerance.
Metabolism and nutritional disorders:
*Less frequent:*Weight gain.
Reproductive system disorders:
Less frequent: Impotence, amenorrhoea, galactorrhoea and gynaecomastia.
Priapism. Inhibition of ejaculation.
Blood disorders:
Less frequent: Haemolytic anaemia, aplastic anaemia, thrombocytopenic purpura and potentially fatal agranulocytosis.
Symptoms such as sore throat or fever should be watched for and white cell counts instituted should they appear.
General disorders:
The following side effects have been reported, but the frequencies are unknown:
Hypersensitivity reactions include urticaria, exfoliative dermatitis, erythema multiforme and contact sensitivity.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms:
See “SIDE-EFFECTS” and “WARNINGS AND SPECIAL PRECAUTIONS”.
Depending on the dose, symptoms vary from restlessness, clouding of consciousness, agitation, confusion and extrapyramidal symptoms to coma and hypotension.
Treatment:
The stomach should be emptied by aspiration and lavage. Further treatment is symptomatic and supportive.

IDENTIFICATION

White capsule containing a white powder.

PRESENTATION

Amber glass bottles or securitainers with 30, 100 or 500 capsules.
Blisters with 30, 100 or 500 capsules.
Sealed aluminium bags with 30 or 100 capsules.

STORAGE INSTRUCTIONS

Store in a dry place at or below 25 °C. Protect from light.
KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER

U/2.6.5/32

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Oethmaan Biosims (Pty) Ltd.
14 Komatie Road
Emmarentia, 2195
Johannesburg

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SO/PI/A

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