NEGATIL TABLET 50MG
NEGATIL TABLET 200MG

NAME AND STRENGTH OF ACTIVE INGREDIENT(S):

NEGATIL TABLET 50MG
Each tablet contains:
Sulpiride ……50mg

NEGATIL TABLET 200MG
Each tablet contains:
Sulpiride……200mg

PRODUCT DESCRIPTION:

NEGATIL TABLET 50MG
A yellow, round, scored of diameter 7mm flat tablet with 'MPI' marking.

NEGATIL TABLET 200MG
An orange, round, scored of diameter 9mm convex tablet with 'MPI' marking.

PHARMACODYNAMICS:
Sulpiride is a substituted benzamide which is claimed to exert its antipsychotic action via a selective blockage of central dopamine D2 receptors.

PHARMACOKINETICS:
Sulpiride is absorbed from the gastro-intestinal tract although bioavailability is low and subject to interindividual variation. It is rapidly distributed to the tissues but passage across the blood brain barrier is poor. Sulpiride is less than 40% bound to plasma proteins and is reported to have plasma half-life of about 7 to 9 hours. It is excreted in the urine chiefly as unchanged drug.

INDICATION:
Sulpiride is indicated for the treatment of schizophrenia and also chronic delusional psychoses.

RECOMMENDED DOSAGE:
Adult: Initial doses of 200-400mg twice daily, increased if necessary up to a maximum of 1-2g twice daily. Doses at the lower end of the range have a greater alerting effect and have been recommended for patients with predominant negative symptoms.
Children: 3-5mg per kg body-weight.
Children under 14 years not recommended.
Elderly: Initiallly quarter to half adult dose.

ROUTE OF ADMINISTRATION:
Oral

CONTRAINDICATIONS:
Contraindicated in patients with pre-existing central nervous system depression or coma, bone-marrow suppression, or phaeochromocytoma, severe hepatic, renal or blood disease and breast-feeding.

WARNINGS AND PRECAUTIONS:
1. It may cause sedative effects and is most marked during the first few days of adminstration; affected patients should not drive or operate machinery.
2. Caution or not at all in patients with impaired liver, kidney, cardiovascular, cerebrovascular and respiratory functions and in those with closed-angle glaucoma, parkinsonism, diabetes mellitus, hypothyroidism, myasthenia gravis, or prostatic hypertrophy. Care is required in epileptic patients receiving anticonvulsant therapy as it may lower the seizure threshold; they should be avoided if possible in untreated epileptics.
3. Elderly and debilitated patients may be more prone to the adverse effects. Sulpiride should be given in reduced doses to elderly patients.
4. Sulpiride should be given with care to manic or hypomanic patients in whom it may exacerbate symptoms.
5. Teratogenic risk of neuroleptics is probably less severe than the possible sequelae of untreated psychotic illness. Intoxication and withdrawal symptoms may oocur in neonates exposed to high doses of antipsychotics towards the end of pregnancy; sedation, hypotonia, extrapyramidal symptoms and cholestatic jaundice have been reported.

INTERACTIONS WITH OTHER MEDICAMENTS:

1. Seizures have been reported in patients using tramadol.
2. When sulpiride was given concomitantly with therapeutic doses of sucralfate, or of an antacid containing aluminium and magnesium hydroxides, in 6 healthy subjects the mean oral bioavaibility of sulpiride was reduced by 40 and 32% respectively. When sulpiride was given 2 hours after the antacid or sucralfate (each in 2 subjects) the reduction in bioavailability was about 25%. This interaction was expected to be clinically siginificant and it was recommended that if used concurrently, sulpiride should be given before, rather than with or after, sucralfate or antacids.
3. Symptoms of central nervous system depression may be enhanced by other drugs with central nervous system depressant properties including alcohol, general anaesthetics, hypnotics and sedatives, and opioid analgesics.

PREGNANCY AND LACTATION:

Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyradimal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required intensive care unit support and prolonged hospitalisation.
Negatil Tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

SIDE EFFECTS:

Sleep disturbances, overstimulation, and agitation may occur. The incidence of extrapyramidal disorders appear to be less than that of chlorpromazine, but claims that sulpiride is less likely to cause tardive dyskinesia remain to be established. Sulpiride is less likely to cause sedation than other neuroleptics and antimuscarinic effects are minimal. Cardiovascular effects such as hypotension are generally rare although they may occur with overdosage.

SYMPTOMS AND TREATMENT OF OVERDOSE:

Symptoms:
Doses of 3 to 7g may produce a degree of agitation, confusion and extrapyramidal symptoms; more than 7g can cause in addition, coma and low blood pressure.
Treatment:
Recent ingestion may be emptied by gastric lavage and activated charcoal administration. Patients should be managed with intensive symptomatic and supportive therapy. May be treated with alkaline osmotic diuresis and, if necessary, anti-parkinsonian drugs.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE:

It may cause sedative effect and is most marked during the first few days of administration; affected patients should not drive or operate machinery.

PRECLINICAL SAFETY DATA:

Not applicable

INSTRUCTION FOR USE:

For oral use only.

DOSAGE FORMS AND PACKAGING AVAILABLE:

NEGATIL TABLET 50MG
Pack size: Blister pack: 50 x10's

NEGATIL TABLET 200MG
Pack size: Blister pack: 50 x10's

NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa,11900 Bayan Lepas,
Pulau Pinang, Malaysia.

DATE OF REVISION:

22/10/2019