Ospolot (Sulthiame)

Product Name
Ospolot

Composition
Sulthiame
The structure of sulthiame is distinct from that of other anticonvulsants. It is a cyclic sulphonamide derivative without antimicrobial activity.

Actions
Anticonvulsant

Indications
Behavioural disorders associated with epilepsy; hyperkinetic behaviour; temporal lobe epilepsy; myoclonic seizures; grand mal attacks; Jacksonian seizures.

Warnings
Ospolot should be administered to patients with impaired renal function only with adequate monitoring. Sulthiame is predominantly renally excreted.

Precautions
Use in Pregnancy: The risk of a mother with epilepsy giving birth to a baby with an abnormality is about three times that of the normal population. Some of this risk is due to the anticonvulsant drugs taken. Mothers taking more than one anticonvulsant drug might have a higher risk of having a baby with a malformation than mothers taking one drug. There is a lack of data permitting any statement that women taking sulthiame are at any different risk of having a baby with an abnormality from women taking other anticonvulsants. Overall, the risk of having an abnormal child is far outweighed by the dangers to the mother and foetus of uncontrolled convulsions. If administered during pregnancy the dose of sulthiame must be kept as low as possible, particularly between days 20 and 40 of gestation.

Use in Lactation: It is not known whether sulthiame is excreted in breast milk nor whether it has a harmful effect on the newborn. Therefore, it is not recommended for nursing mothers unless the expected benefits outweigh any potential risk.

Adverse Reactions: More common reactions: Ataxia, paraesthesia of the face and extremities, hyperpnoea, dyspnoea, anorexia.

Less Common Reactions: Giddiness, rash, Stevens-Johnson syndrome, nausea, abdominal. weight loss, leucopenia, headache, psychic changes, depression, drooling, increased pain, frequency of fits, insomnia, status epilepticus. Disturbances in calcium and vitamin D metabolism have been occasionally reported in association with long-term anticonvulsant therapy.

Interactions: Alcohol must not be consumed during treatment.
The concomitant use of sulthiame and primidone may lead to severe side-effects, including psychotic reactions. The addition of sulthiame to pre-existing phenytoin therapy has shown to be followed by a rise in the serum levels of phenytoin. It has been suggested that this may be due to either to inhibition by sulthiame of the hydroxylation of phenytoin or to displacement of phenytoin from a storage site by sulthiame. Phenytoin dosage may need to be reduced when sulthiame is added.

Sulthiame may also induce a rise in the serum level of phenobarbitone.

Sulthiame may interfere with the estimation of barbiturates in laboratory tests on blood.

Overdosage
Clinical features have included vomiting, hypotension, headache, vertigo, ataxia, metabolic acidosis with hyperpnoea and catatonic state.
There is no specific antidote. Treatment consists of general supportive measures including intravenous fluids. The urine should be rendered alkaline to prevent crystalluria; forced alkaline diuresis may promote elimination of sulthiame.

There is no information on the applicability of dialysis.

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Dosage and Administration
Treatment should start with a low dosage which is gradually increased until clinical response is satisfactory. This may require four weeks. Ospolot tablets should preferably be swallowed whole with a little fluid after meals.
Adults: Initially 100mg twice daily or 50mg three times daily (optimum: 200mg three times daily)

Children: Initially 3-5mg/kg daily in equal divided doses (optimum:10-15mg/kg daily in equal divided doses)

Caution should be used when establishing dosage in the presence of renal or hepatic impairment.

Presentation
Tablets, 50mg: (white, film-coated and coded 50 on one side) (200 per bottle)
Tablet description amended 9/99. AUST R 18847 Catalogue No.: TAB002

Tablets, 200mg: (white, film-coated, scored and coded 200 on reverse) (200 per bottle)
Tablet description amended 9/99. AUST R 18848 Catalogue No.: TAB003

Poison Schedule
All States and Territories in Australia - S4

Reference
TGA Approved June 1990

Sponsor
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