

HYPOTHAL

Capsules

Composition

Each capsule contains Sulpride 50 mg.

Action

Sulpride is a substituted benzamide, unrelated chemically to other dopamine receptor antagonists of the phenothiazine, butyrophenone or thioxanthene groups. Sulpride demonstrates pronounced antipsychotic activity as well as peripheral activity on the gastrointestinal system.

An antipsychotic agent, it shares some common properties with the "classical" neuroleptics (e.g. haloperidol, chlorpromazine). However, as shown in biochemical and behavioural laboratory studies, it also differs from them in several fundamental respects, especially based on its selectivity for dopamine receptors and relatively limited interference with other neuronal pathways. Sulpride is effective clinically in most forms of depression, especially in the true psychoses. It also has an important thymo-analeptic component. It is of value in the treatment of autism, phobic conditions and vertigo of various types. The effect on vertigo is due to its selective tropism in the central nervous system, and its involvement in the vestibular area.

Sulpride stimulates gastrointestinal motility, but this effect is less pronounced than that of metoclopramide. There is no clear indication that peripheral or central dopamine receptors, or both, are involved in the gastrointestinal effects of Sulpride. Anti-ulcer activity has been observed in a variety of experimental models. Sulpride is used successfully clinically in the treatment of stress ulcers and produces favourable effects in the healing of peptic ulcers, mainly by improving functional disturbances of the gastrointestinal tract and, hence, relieving pain. It also has antiemetic properties and inhibits gastric secretion.

The average serum half-life of Sulpride is 8 hours. About 70% of the dose is recovered in the urine within 36 hours.

Indications

Psychiatry

- Psychoses of schizophrenia, of both organic and confusional origin. Pre-psychotic states. Schizophrenic states with symptoms of apathy and apragmatism.
- In cases of delusional and hallucinatory states and in cases of non-acute agitation, Hypothal should be combined with a sedative neuroleptic (e.g. levopromazine).
- Acute confusional states, phobias.
- Depressive states of various origins, including geriatric cases.
- Neurosis with psychomotor inhibition.
- Childhood psychoses and pre-psychotic states.
- Autistic behavioural disturbances.

Gastroenterology

In peptic ulcer and as an adjuvant in functional disturbances of the gastrointestinal tract.

Vertigo

- Vertigo of cochlear and vestibular origin (chronic otitis following mastoid operation, fractures of the temporal bone, etc.).
- Meniere's syndrome.
- Vertigo of vascular origin (due to basilar artery stenosis, Wallenberg's syndrome, cervical arthritis and Barre-Lieou's syndrome).
- Vertigo due to cranial or cervical trauma and due to the action of ototoxic drugs.

Contraindications

- Known hypersensitivity to the drug. States of acute agitation and mania.

- Parkinsonism. Suspected or existing pheochromocytoma.

Warnings

Pregnancy and Breastfeeding

Safety of use has not been established.

Adverse Reactions

Dyskinesias and extrapyramidal syndromes may occur; they respond quickly to parenteral treatment with central anticholinergics. Sedation or somnolence may appear. Reversible galactorrhoea and amenorrhoea due to elevated prolactin levels have been reported. Over stimulation and agitation may occur.

Gastrointestinal disturbances, tachycardia and moderate falls in blood pressure have also been reported, but rarely.

Precautions

Caution is recommended in cases of high blood pressure, severe cardiac disease, renal and liver impairment, ataxia and epilepsy.

Patients experiencing drowsiness at the beginning of and during treatment should be cautioned against engaging in potentially hazardous activities requiring mental alertness, such as driving a car or operating machinery.

Drug Interactions

Sulpride may potentiate the action of hypotensive and antihypertensive drugs as well as antidepressants, and CNS depressants such as hypnotics, tranquilizers, anaesthetics and analgesics.

Dosage and Administration

Psychiatry

In adults, the dosage is from 6-12 capsules daily.

In children, the initial dosage is 5 mg/kg body weight/ day orally, divided into 3 equal doses. The maintenance dosage is 5-10 mg/kg body weight orally over 24 hours, in divided doses.

Gastroenterology

For acute states, administer 4-6 capsules during 24 hours, for a period of 8-15 days.

The maintenance dosage is 3 capsules administered over 24 hours.

In the consolidation period, administer 1-3 capsules over 24 hours, for a period of 21 days.

Vertigo

The average dosage is 3-6 capsules daily.

In severe cases, the dosage may be increased or the intramuscular route may be employed. The duration of treatment should not be less than 15 days, and should be continued for several weeks when necessary.

Over Dosage

Manifestations

Severe Parkinson-like syndrome, coma.

Treatment

Consists of gastric lavage, symptomatic treatment; antiparkinsonism drugs parenterally, if necessary.

Presentation

Box of 20 capsules.