Hydergine® Tablets 1.5mg

Activation of cerebral metabolism

Composition
Co-dergocrine mesylate* (BAN)

Tablets	1.0, 1.5 or 4.5mg
Oral Solution	
1 ml=20 drops	1.0 mg
Oral Solution	
1 ml=20 drops	3.0 mg
Ampoules (1 ml)	0.3 mg

*Composed of equal parts of the mesylates of dihydroergocornine, dihydroergocristine and dihydroergocryptine (dihydro-α-ergocryptine and dihydro-β-ergocryptine in the proportion 2 to 1).

Properties
Animal studies indicate that Hydergine modifies cerebral neurotransmission, and evidence is available for a stimulant effect on dopamine and serotonin receptors and for a blocking effect at α-adrenoceptor sites. It improves impaired cerebral metabolic function, an effect which is reflected in changes in the electrical activity of the brain, notably in the power spectra of the electroencephalogram. This beneficial effect on the EEG has been confirmed by experimental studies in man. Hydergine has also been found to shorten cerebral circulation time.
Controlled clinical trials have shown that Hydergine is effective in improving many of the symptoms of mental deterioration, especially agerelated symptoms in the areas of selfcare, social behaviour, emotional state and mental performance.
Hydergine also has a stabilizing effect on the tone of cranial vessels, and this accounts for its prophylactic effect in migraine.
Its beneficial effect in peripheral vascular disorders and on subjective symptoms associated with arterial hypertension is considered to be due to its dilator effect on precapillary sphincters and its α-adrenoceptor blocking activity.

Pharmacokinetics
The absorption of Hydergine after oral administration amounts to 25%. Maximal plasma concentrations are reached after 0.5 to 1.5 hours. Due to the first-pass effect, the bioavailability is between 5 and 12%. The volume of distribution is 1100 l (approx. 16 l/kg) and the plasma-protein binding 81%. The elimination is biphasic with a short half-life of 1.5 to 2.5 hours (α-phase) and a longer one of 13 to 15 hours (β-phase). Hydergine is mainly excreted with the bile into the faeces. Elimination in the urine amounts to 2% for the unchanged drug and its metabolites and to less than 1% for the unchanged substance alone. Total clearance is about 1800 ml/min. In elderly patients the plasma concentrations are somewhat higher than in younger subjects. In patients with renal insufficiency, a reduction in dose is scarcely necessary because only a minor amount of the drug and its metabolites is eliminated by the kidney.

Indications

- Symptoms and signs of mental deterioration notably those related to ageing: dizziness, headache, poor concentration, disorientation, impaired memory, lack of initiative, mood depression, unsociability, difficulties with daily living activities and with self-care,
- Acute cerebrovascular disease,
- Migraine and vascular headaches (preventive treatment only),
- Peripheral vascular disorders,
- Subjective symptoms associated with arterial hypertension.

Dosage

Orally:
3 to 6 mg daily, in divided doses, preferably before meals. For once-a-day dosage 1 tablet of 4.5 mg or 1.5 ml (30 drops) of the 3 mg/ml oral solution are recommended before breakfast unless otherwise prescribed by the physician. In patients with mental deterioration or with migraine, the alleviation of symptoms is usually gradual and becomes manifest after 3 to 4 weeks. Prolonged therapy (3 months or more) is indicated and the course of treatment may be repeated as required.

Parenterally:
In acute cerebrovascular disorders (especially when associated with hypertension) parenteral therapy is indicated initially in addition to oral treatment:0.3 mg (1 ml) Hydergine by i.v. drip or slow i.v. injection (in 20 ml dextrose or saline) once or twice daily. Alternatively, 0.3 mg (1 ml) may be given intramuscularly or subcutaneously once to several times daily. In severe cases of peripheral vascular disease, 0.3 to 0.6 mg (1 to 2 ml) intramuscularly or subcutaneously once or twice daily, in addition to oral treatment. If necessary, Hydergine may also be given by intra-arterial injection (0.3 to 0.6 mg=1 to 2 ml), preferably diluted in 10-20 ml saline.

Contraindication
Known hypersensitivity to the drug.

Precautions
Caution is required in the presence of severe bradycardia. Blood pressure should be checked following parenteral administration, as a drop in blood pressure may occur. Hydergine should be kept out of reach of children.

Side effects
Nasal stuffiness; transient nausea and gastric upsets may occur occasionally, but are usually prevented by taking the drug with food. In the majority of cases side effects disappear without specific measures being taken.

Treatment of overdosage
No cases with severe signs or symptoms of overdosage are known.

Packing
100 tablets and 500 tablets

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Hsin-Chu plant
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