

HEPA-MERZ

Merz Pharmaceuticals GmbH

Composition

Hepa-Merz Infusion Concentrate

1 ampoule of 10 ml contains 5 g L-ornithine-L-aspartate as active ingredient.

Excipient: Water for injection.

Hepa-Merz Granules

1 sachet of 5 g contains 3 g L-ornithine-L-aspartate as active ingredient.

Excipients: Anhydrous citric acid, saccharin sodium, sodium cyclamate, povidone K25, fructose, flavors and colouring agent E110.

Indications

Infusion Concentrate:

For the treatment of hyperammonemia as a result of acute and chronic liver diseases such as liver cirrhosis, fatty liver, hepatitis; especially for the treatment of incipient disturbances of consciousness (pre-coma) or neurological complications (hepatic encephalopathy).

Granules:

For the treatment of concomitant diseases and sequelae of acute and chronic liver diseases (e.g. liver cirrhosis) with the symptoms of latent and manifest hepatic encephalopathy.

Contraindication

Hypersensitivity to L-ornithine-L-aspartate or any other excipients of these products.

Severe renal insufficiency (a serum creatinine level in excess of 3 mg/100 ml can be regarded as the guide value).

Special warnings and precautions:

Infusion Concentrate:

Administration of high doses requires monitoring of serum and urinary urea levels. If liver function is substantially impaired, the infusion rate must be adjusted to the individual patient in order to prevent nausea and vomiting.

Granules:

Patients with rare hereditary problems of fructose intolerance should not take this medicine. Hepa-Merz granules contain 1.13 g fructose per sachet (equivalent to 0.11 CEU). This should be taken into account in patients with diabetes mellitus.

Hepa-Merz granules may be harmful to the teeth (caries) in long-term use.

Pregnancy and lactation:

The administration in pregnancy and lactation should be avoided. If treatment is nevertheless thought to be necessary, the benefits and risks should be carefully assessed.

Side Effects

Infusion Concentrate: uncommon nausea; rare vomiting

Granules: uncommon nausea, vomiting, stomach ache, flatulence, diarrhoea; very rare pain in the limbs. E110 can trigger allergic reactions.

Dosage and Administration

Infusion Concentrate:

Up to 4 ampoules can be applied daily. In precoma and coma up to 8 ampoules within 24 hours as initial treatment, depending on the severity of the condition.

Infusion Rate:

5 g/h at maximum.

Granules:

1-2 sachets (dissolved in a glass of water, juice or tea) up to 3 times a day at mealtimes.