

PACKAGE LEAFLET: INFORMATION FOR THE USER

Hepa-Merz infusion concentrate, 5 g/ampoule, concentrate for solution for infusion L-ornithine-L-aspartate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Hepa-Merz infusion concentrate is and what it is used for
2. Before you use Hepa-Merz infusion concentrate
3. How to use Hepa-Merz infusion concentrate
4. Possible side effects
5. How to store Hepa-Merz infusion concentrate
6. Further information

1. WHAT HEPA-MERZ INFUSION CONCENTRATE IS AND WHAT IT IS USED FOR

Hepa-Merz infusion concentrate is a medicine which stimulates ammonia detoxification by increasing urea synthesis in the liver. Furthermore, it serves ammonia detoxification in the tissues outside the liver.

Hepa-Merz infusion concentrate is used in the treatment of depression of consciousness due to liver failure (latent and manifest hepatic encephalopathy).

2. BEFORE YOU USE HEPA-MERZ INFUSION CONCENTRATE

Do not use Hepa-Merz infusion concentrate

- if you react hypersensitively (allergically) to L-ornithine-L-aspartate
- if you suffer from severely impaired kidney function (renal insufficiency). A serum creatinine value over 3 mg / 100 ml can be used as a guideline value.

Take special care with Hepa-Merz infusion concentrate

- if high doses of Hepa-Merz infusion concentrate are used. The urea level in the serum and urine should be monitored by your doctor.
- if liver function is severely impaired. In order to avoid nausea and vomiting, your doctor will adjust the infusion rate on an individual basis.

No data are so far available on the use of the drug in children.

Taking other medicines:

Please tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including medicines obtained without a prescription.

To date, no interactions are known.

Pregnancy and breast-feeding

Safety of use of Hepa-Merz infusion concentrate has not been established during pregnancy and lactation. If you wish to become pregnant, are already pregnant or are breastfeeding, please inform your doctor.

Ask you doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

As a result of your illness, your ability to drive and use machines may be impaired during treatment with Hepa-Merz infusion concentrate.

3. HOW TO USE HEPA-MERZ INFUSION CONCENTRATE

Unless otherwise prescribed by your doctor, the usual dose is up to 4 ampoules daily.

On initial depression of consciousness (precoma) and clouding of consciousness (coma), your doctor may administer up to 8 ampoules within 24 hours depending upon the severity of the condition.

Mode of administration:

Hepa-Merz infusion concentrate is a concentrate for solution for infusion.

Prior to use, your doctor will add the ampoule contents to a solution for infusion and will infuse Hepa-Merz infusion concentrate in this form.

Hepa-Merz infusion concentrate can be easily mixed with the usual infusion solutions. On grounds of venous compatibility, however, your doctor should dissolve no more than 6 ampoules per 500 ml infusion.

The maximum infusion rate is 5 g L-ornithine-L-aspartate (corresponding to the contents of one ampoule) per hour.

Hepa-Merz infusion concentrate may not given as an intra-arterial administration.

If you have the impression that the effect of Hepa-Merz infusion concentrate is too strong or too weak, please talk to your doctor or pharmacist.

If you use more Hepa-Merz infusion concentrate than you should:

No signs of intoxication have been observed following an overdose of L-ornithine-L-aspartate so far. If necessary your doctor will treat the symptoms.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Hepa-Merz infusion concentrate can cause side effects, although not everybody gets them.

The following table is placed at the beginning of this section for clarification:

Very common:	More than 1 of 10 people treated
Common:	less than 1 of 10, but more than 1 of 100 people treated
Uncommon:	less than 1 of 100, but more than 1 of 1,000 people treated
Rare:	less than 1 of 1,000, but more than 1 of 10,000 people treated
Very rare:	less than 1 of 10,000 people treated, or unknown

Possible side effects of Hepa-Merz infusion concentrate:

Uncommon: Nausea

Rare: Vomiting

These side effects are generally transient, however, and do not require discontinuation of the medicine. They resolve following a dose reduction or reduction of the infusion rate.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE HEPA-MERZ INFUSION CONCENTRATE

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date given on the outer carton/container.

Do not store above 25°C.

6. FURTHER INFORMATION

What Hepa-Merz infusion concentrate contains

The active substance is L-ornithine-L-aspartate.

1 ampoule with 10 ml contains 5 g L-ornithine-L-aspartate.

The other ingredient is water for injections.

What Hepa-Merz infusion concentrate looks like and contents of the pack

Hepa-Merz infusion concentrate is a clear solution.

Hepa-Merz infusion concentrate is available in packs containing 5, 10, 25 and 30 ampoules with 10 ml concentrate for solution for infusion.

Not all pack sizes may be marketed.

Marketing Authorization Holder: Merz Pharmaceuticals GmbH, Eckenheimer Landstr. 100, 60318 Frankfurt, Germany

Manufacturer: Merz Pharma GmbH & Co. KGaA, Eckenheimer Landstr. 100, 60318 Frankfurt, Germany

This leaflet was last approved on {}.