

**This is a translation of the German package leaflet and has only exemplary character. Please ask your local authorities or manufacturer/distribution partner for country-specific patient information.**

**Package leaflet: Information for the user**

**Hepa-Merz 5 g / 10 ml 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.
- If get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. What Hepa-Merz concentrate for solution for infusion is and what it is used for
2. What you need to know before you use Hepa-Merz concentrate for solution for infusion
3. How to use Hepa-Merz concentrate for solution for infusion
4. Possible side effects
5. How to store Hepa-Merz concentrate for solution for infusion
6. Contents of the pack and other information

**1. What Hepa-Merz concentrate for solution for infusion is and what it is used for**

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

**2. Before you use Hepa-Merz concentrate for solution for infusion**

**Do not use Hepa-Merz concentrate for solution for infusion**

- 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 concentrate for solution for infusion**

- if high doses of Hepa-Merz concentrate for solution for infusion 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.

**Children**

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

**Other medicines and Hepa-Merz concentrate for solution for infusion**

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 concentrate for solution for infusion 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 your 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 concentrate for solution for infusion.

### **3. How to use Hepa-Merz concentrate for solution for infusion**

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 concentrate for solution for infusion 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 concentrate for solution for infusion in this form.

Hepa-Merz concentrate for solution for infusion can be mixed with the usual infusion solutions. So far no peculiarities have been observed with regard to miscibility. Your doctor should prepare the mixture only immediately before application. 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 concentrate for solution for infusion may not be given as an intra-arterial administration.

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

### **If you use more Hepa-Merz concentrate for solution for infusion 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 concentrate for solution for infusion can cause side effects, although not everybody gets them.

#### **Possible side effects are**

Uncommon: Nausea

Rare: Vomiting

Frequency not known: Hypersensitivity, allergic (anaphylactic) reaction

Nausea and vomiting are generally transient and do not require discontinuation of the medicine. They resolve following a dose reduction or reduction of the infusion rate.

Side effects are classified according to the following frequency data:

<b>Very common:</b>	may affect more than 1 of 10 people
<b>Common:</b>	may affect up to 1 of 10 people
<b>Uncommon:</b>	may affect up to 1 of 100 people
<b>Rare:</b>	may affect up to 1 of 1,000 people
<b>Very rare:</b>	may affect up to 1 of 10,000 people
<b>Not known:</b>	frequency cannot be estimated from the available data

### Reporting of side effects

If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. **You can also report side effects directly to your national reporting system.**

**Bundesinstitut für Arzneimittel und Medizinprodukte**  
 Abt. Pharmakovigilanz  
 Kurt-Georg-Kiesinger Allee 3  
 D-53175 Bonn  
 Website: <http://www.bfarm.de>.

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Hepa-Merz concentrate for solution for infusion

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 30°C.

### 6. Contents of the pack and other information

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

Hepa-Merz concentrate for solution for infusion is a clear solution.  
 Hepa-Merz concentrate for solution for infusion 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 Landstraße 100, 60318 Frankfurt, Germany

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

This leaflet was last revised **in 01/ 2015.**