

**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 granules, 3 g, granules for oral solution**

L-ornithine-L-aspartate

**Read all of this leaflet carefully before you start using this medicine, because it contains important information for you.**

Always take this exactly as described in this leaflet or as your doctor or pharmacist has told to you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes side effects, not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

#### **In this leaflet:**

1. What Hepa-Merz granules are and what they are used for
2. What you need to know before you take Hepa-Merz granules
3. How to take Hepa-Merz granules
4. Possible side effects
5. How to store Hepa-Merz granules
6. Contents of the pack and other information

#### **1. WHAT HEPA-MERZ GRANULES ARE AND WHAT THEY ARE USED FOR**

Hepa-Merz granules are 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 granules are used in the treatment of co-existing and subsequent disorders resulting from impaired detoxification activity in the liver (e.g. in cirrhosis of the liver) with symptoms of latent and manifest hepatic encephalopathy.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE HEPA-MERZ GRANULES**

##### **Do not take Hepa-Merz granules**

- if you react hypersensitively (allergically) to L-ornithine-L-aspartate, orange yellow S (E 110) or any of the other ingredients of Hepa-Merz granules
- 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

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Hepa-Merz Granules.

##### **Children**

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

### **Other medicines and Hepa Merz granules**

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.

No interactions are known so far.

### **Pregnancy and breast-feeding:**

Safety of use of Hepa-Merz granules has not been established during pregnancy. If you are pregnant, you should therefore only take Hepa-Merz granules if directed by your doctor.

It is not known whether the active substance contained in Hepa-Merz granules crosses into the breast milk. If you are breast-feeding, you should therefore only take Hepa-Merz granules if directed by 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 granules.

**Hepa-Merz granules contain fructose.** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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 in long-term use (caries).

## **3. HOW TO TAKE HEPA-MERZ GRANULES**

Always take Hepa-Merz granules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the usual dose is as follows:

Take the dissolved contents of 1 - 2 sachets of Hepa-Merz granules, up to 3 times daily.

### **Mode of administration:**

Hepa-Merz granules should be dissolved in plenty of fluid (e.g. a glass of water, tea or juice) and taken with or after meals.

The ready to use solution should be used immediately following preparation.

### **If you take more Hepa-Merz granules than you should:**

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

### **If you forget to take Hepa-Merz granules:**

Do not take a double dose to make up for a forgotten dose.

Just take the next dose at the correct time, as described in the dosage instructions.

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 granules can cause side effects, although not everybody gets them.

*Possible side effects of Hepa-Merz granules:*

Gastrointestinal disorders

Uncommon: Nausea, vomiting, stomach ache, flatulence, diarrhoea  
Musculoskeletal and connective tissue disorders

Very rare: Pain in the limbs

These side effects are usually transient and do not require withdrawal of the medicine.

Hepa-Merz granules contain the colouring agent orange yellow S (E 110). Orange yellow S can trigger allergic reactions.

**Side effects are classified according to the following frequency data:**

Very common	may affect more than 1 of 10 people
Common	may affect up to 1 of 10 people
Uncommon	may affect up to 1 of 100 people
Rare	may affect up to 1 of 1,000 people
Very rare	may affect up to 1 of 10,000 people
Not known	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 GRANULES

Keep out of the reach and sight of children.

Do not use Hepa-Merz granules after the expiry date which is stated on the outer carton/container.

Do not store above 25°C.

*[For climatic zones III/IV "Do not store above 30°C."]*

#### 6. CONTENT OF THE PACK AND OTHER INFORMATION

**What Hepa-Merz granules contain:**

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

1 sachet with 5 g granules for oral solution contains 3 g L-ornithine-L-aspartate.

The other ingredients are citric acid, saccharin sodium, sodium cyclamate, fructose, povidone 25, flavourings, colouring agent orange yellow S (E 110).

**What Hepa-Merz granules look like and contents of the pack:**

The granules are orange in colour.

Hepa-Merz granules are available in packs containing 10, 30, 50, 100 and 250 sachets of granules.  
Not all pack sizes may be marketed.

**Marketing authorization holder:** Merz Pharmaceuticals GmbH, Eckenheimer Landstraße 100,  
60318 Frankfurt/Main, Germany

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

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