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.
- 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 granules are and what they are used for
2. 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. Further 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. 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

Take special care with Hepa-Merz granules
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.
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 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 granules.

Important information about some of the ingredients of Hepa-Merz granules:
This medicine contains 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.

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.

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 granules:
Uncommon: Nausea, vomiting, stomach ache, flatulence, diarrhoea
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.

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 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℃.

6. FURTHER 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, Germany

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

This leaflet was last approved on ( )