

PACKAGE LEAFLET: INFORMATION FOR THE USER

**Lornit 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 Lornit infusion concentrate is and what it is used for
2. Before you use Lornit infusion concentrate
3. How to use Lornit infusion concentrate
4. Possible side effects
5. How to store Lornit infusion concentrate
6. Further information

1. WHAT LORNIT INFUSION CONCENTRATE IS AND WHAT IT IS USED FOR

Lornit 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.

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

2. BEFORE YOU USE LORNIT INFUSION CONCENTRATE

Do not use Lornit infusion concentrate

- if you react hypersensitively 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 Lornit infusion concentrate

- if high doses of Lornit 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 Lornit 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 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 Lornit infusion concentrate.

3. HOW TO USE LORNIT 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:

Lornit 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 Lornit infusion concentrate in this form.

Lornit 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.

Lornit infusion concentrate may not be given as an intra-arterial administration.

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

If you use more Lornit 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, Lornit infusion concentrate can cause side effects, although not everybody gets them.

Possible side effects of Lornit 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.

Reporting of side effects

- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top of the home page.
- By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE LORNIT 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 Lornit infusion concentrate contains

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

Each ml contains: L-Ornithine L-Aspartate 0.5 gm

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

The other ingredient is water for injections.

What Lornit infusion concentrate looks like and contents of the pack

Lornit infusion concentrate is a clear solution.

An ampoule of 10 ml.

Marketing Authorization Holder

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