Package Leaflet: Information for The User

Lornit Sachet

granules for Oral Administration
(L-Ornithine-L-Aspartate granules)

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

1. WHAT LORNIT SACHET ARE AND WHAT THEY ARE USED FOR

Lornit sachet 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.

Lornit sachet 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 LORNIT SACHET

Do not take Lornit sachet

- if you react hypersensitively (allergically) to L-Ornithine-L-Aspartate, or any of the other ingredients of Lornit sachet
- 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 Lornit sachet.

Children

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

Other medicines and Lornit sachet

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 Lornit sachet has not been established during pregnancy. If you are pregnant, you should therefore only take Lornit sachet if directed by your doctor.
It is not known whether the active substance contained in Lornit sachet crosses into the breast milk. If you are breast-feeding, you should therefore only take Lornit sachet 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 Lornit Sachet.

3. HOW TO TAKE LORNITGRANULES

Always take Lornit sachet 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 Lornit sachet, up to 3 times daily.

Mode of administration:

Lornit sachet 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 Lornit Sachet 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 Lornit Sachet:

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, Lornit Sachet can cause side effects, although not everybody gets them.

Possible side effects of Lornit Sachet:
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.

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. 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 SACHET

Keep out of the reach and sight of children.

Do not use Lornit sachet after the expiry date which is stated on the outer carton/container.

Do not store above 25°C.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Lornit Sachet contain:
The active substance is L-ornithine-L-aspartate.
1 sachet with 3.25 g g granules for oral solution contains 3 g L-ornithine-L-aspartate.

The granules are Sunset Yellow FCF in colour.
10 Sachets of 3.25 g each

Marketing authorization holder

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