

## 30-03-2022 1st Copy



L-Ornithine L-Aspartate +Nicotinamide + Riboflavin -5-Phosphate Sodium

Levijon® <sub>Injection</sub>

(L-Ornithine L-Aspartate)

Concentrate for Infusion

(L-Ornithine L-Aspartate)

#### QUALITATIVE AND QUANTITATIVE COMPOSITION

**Levijon<sup>®</sup> Syrup** Each 5ml contains: L-Ornithine L-Aspartate MS..... ...... 300ma Riboflavin-5-Phosphate Sodium BP...... 0.765mg

**Levijon**® Injection Each 5ml contains: L-Ornithine L-Aspartate MS......500mg Levijon® Concentrate For Infusion L-Ornithine L-Aspartate MS.....

PHARMACEUTICAL FORM

Syrup/Injection/Concentrate for infusion.

#### CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS:

Acute to chronic hepatitis (with or without hyperammonemia), liver cirrhosis, fatty liver with hyperammonemia, hepatic encephalopathy and as an adjuvant therapy with all hepatotoxic drugs.

#### POSOLOGY AND METHOD OF ADMINISTRATION:

- Syrup:

  Adults: Two tablespoonfuls or 30ml twice a day or as prescribed by the physician.
- Children: One teaspoonful or 5ml twice a day or as prescribed by the physician
   Maintenance therapy: As prescribed by the physician.

### Concentrate for Infusion:

Adult:

- Acute hepatitis: 1-2 ampoules a day.
- In chronic hepatitis and hepatic cirrhosis: 2-4 ampoules a day.
   In Hepatic encephalopathy (mild to moderate) upto 8 ampoules within 24 hours.

**Levijon®** Infusion Concentrate can safely be mixed with conventional infusion vehicles. (Infusion rate 5g per hour at the maximum).

Children: No clinical data available below 8 years of age.

OR

As prescribed by the physician

## Injection:

- Injection is injected slowly by the intravenous route.
- During the first week, a daily dose of 2 ampoules, one morning and one evening to be continued for 3-4 weeks.
- The treatment may be continued intermittently, with-alternating weeks of oral therapy.
- It is also quite permissible to make individual dose adjustments

As prescribed by the physician

### CONTRAINDICATIONS:

- Contraindicated in patients with known hypersensitivity to active substances.
- Severe renal insufficiency.

### SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

In patients with severe renal insufficiency, blood urea and serum creatinine must be monitored regularly, serum creatinine value exceeding 3mg/ml is regarded as a reference

### PREGNANCY AND LACTATION:

Not enough is known during pregnancy and breast-feeding. Avoid use.

## UNDESIRABLE EFFECTS:

Nausea, vomiting, cough, muscle cramp and diarrhoea.

## PHARMACOLOGICAL PROPERTIES

PHARMACOKINETIC PROPERTIES:

Levijon® is a stable combination of two important endogenous amino acids, L-Ornithine and L-Aspartate. After administration it quickly breaks down into L-Ornithine and L-Aspartate. L-Omithine being a substrate of urea cycle, converts toxic ammonia into non-toxic urea which is eliminated via kidneys, helping the diseased liver to carry out its normal function smoothly (DETOXIFICATION). This process lowers the elevated level of ammonia in blood (hyperammonemia) which is a common problem in most of the liver diseases. L-Aspartate is an essential component of citric acid cycle which liberates energy (ATP), and thus helps in regeneration of damaged liver cells.

## SHELF LIFE

**210mm** 



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R.N-08/NA/03/2022