BARSELIV

Instructions for the medicinal product

Trade name: Barseliv.
International Nonproprietary Name: L-Ornithine - L-Aspartate.
Dosage form: Solution for Injection.
Composition: Each 10 ml contains:
L-Ornithine-L-Aspartate 5 g;
Water for injection BP q.s.
Pharmacotherapeutic group: Cholagogues and hepatic.
ATC Classification: A05BA06.
Pharmacologic property:
Pharmacodynamics:
Physiologically nitrogen compounds are metabolized through the urea cycle to be eliminated in the form of ammonium by the kidney.
In liver changes that severely injured in the parenchyma of the liver, the ability of the urea cycle is reduced, which favors the blood concentration of nitrogen compounds.
Thus, the L-ornithine L-aspartate by its metabolic properties induce a stimulation in the urea cycle. This process starts when within mitochondria reacts with ornithine to produce citrulline carbomoilfosfato, which binds to the aspartate in the cytoplasm, becoming argine succinate, which in turn is subdivided into arginine and fumaric acid.
This generated arginine is hydrolyzed, releasing urea and ornithine, which rejoins for a new cycle and promotes the transformation of more nitrogen compounds in urea.
Moreover, the aspartate metabolic channel promotes protein synthesis of pyrimidines, which promotes hepatocellular regeneration, and also acts as a stabilizing molecule in the tricarboxylic acid cycle by preventing the accumulation of lipids in the hepatocyte, thereby reversing the process of hepatic steatosis or fatty liver.
Pharmacokinetics:
Distribution and biotransformation:
After intravenous application, the component L-aspartate is transformed by three major metabolic pathways: Incorporation into tissue proteins by protein synthesis; Energy production, glycogen and triglycerides intermediary metabolism; Transformation into nonessential amino acids and other hydrogen compounds.
For its part, L-ornithine is also metabolized by three mechanisms: As an intermediate in the urea cycle; For the decarboxylation enzyme for synthesis of polyamides (small nitrogen compounds involved in the regulation for the synthesis of proteins); By transamination, resulting in O-glutamate semialdehyde and glutamic acid.
Elimination: Over the course of the catabolism of amino acids, the amino group is used in the urea cycle, forming it, which is excreted by the kidneys. Circulating amino acids are filtered by the nephrons and reabsorbed by active transport system through the proximal tubule.
Indications for use:
In hyperammonemia as a result of acute and chronic liver diseases such as:
- liver cirrhosis;
- fatty liver;
- hepatitis;
- especially for the treatment of incipient disturbances of consciousness (pre-coma) or neurological complications (hepatic encephalopathy).

Since ornithine aspartate exerts its action in the metabolic cycles of the liver, elevated blood ammonia levels are rapidly lowered. The capacity of detoxification, particularly of the urea cycle, is enhanced.
Contraindications:
- hypersensitivity to L-ornithine-L-aspartate or any other excipients of these products;
- severe renal insufficiency (a serum creatinine level in excess of 3mg/100ml can be regarded as the guide value);
- during lactation.

Pregnancy:
No adverse reactions have been found to be amino acids, so there are no contraindications for use during pregnancy.
Dosage and directions for use:
For reasons of venous tolerance, should not more than 4 vials dissolved in 500 ml of solution.
In case of acute liver inflammation (acute hepatitis), recommended 8 vials a day.
In the pre-coma and hepatic coma may apply depending on the degree of severity up to 20 vials diluted in large volume during the first day, according to the following dosage schedule that has proven effective:
8 vials for 6 hours, then 4 vials pass for 6 hours last administration can repeat this twice more to complete the 20 vials in one day.
Duration of infusion, frequency, and duration of treatment is determined individually.
Maximum infusion rate - 5 g / h
It is recommended to dissolve a maximum of 60 ml (6 vials) of the drug in 500 ml of infusion solution.
Side-effects:
Digestive system: in specific cases- nausea, vomiting.
Other: allergic reactions.
Overdose:
Intensification of the above described adverse effects is possible.
Drug interactions:
Barseliv must not be mixed with other medicinal products.
Cautions:
Special guidelines: If nausea or vomiting occurs, it is necessary to optimize the infusion speed. Use only continuous infusion by slow drip.
Infusion of high doses of Barseliv requires, monitoring of serum and urinary urea levels.
Effects on ability to drive and use machines:
Preparation is prescribed with prudence to patients, involved in potentially dangerous activities, demanding increased reaction and quickness of psychomotor action.
Presentation:
1x5, 10 ml ampoule in a white color plastic tray in carton box with instruction for use.
Storage:
Keep in dry place, protected from light at a temperature below 25°C. Keep out of reach of children.
Shelf life:
Labeled. Do not use after expiry date.
Distribution Condition:
Prescribe medicine.

Manufactured for:
SPEY MEDICAL
London, United Kingdom
Manufactured by:
Brawn Laboratories Ltd.
13, New Industrial Township,
Faridabad-121001, Haryana, India