CO_2. A decrease of urea synthesis in acidosis is followed by bicarbonate sparing and the excretion of ammonium ions into urine (renal ammonia-genesis). Glutamine serves in the transport of ammonia from liver to kidney. In acidosis, flux through the urea cycle and hepatic glutaminase is decreased, whereas flux through hepatic glutamine synthetase and renal glutaminase is increased

Pharmacodynamic Effects of LOLA on Ammonia Metabolism

The effects of LOLA on hyperammonemia and urea metabolism in cirrhotic rats were extensively investigated in additional experimental animal studies. Cirrhosis was induced by carbon tetrachloride (Ccl_4). In cirrhotic animals, the activities of carbamoyl phosphate synthetase and arginase were lowered, indicating reduced functioning of the urea cycle. Administration of LOLA significantly increased the activity of these enzymes by 30% and 40%, respectively. At the same time, there was a significant increase in urea production. The decrease in ammonia concentration was also significant. It was concluded from these results that treatment of cirrhotic rats with LOLA increases urea synthesis and, thus, the capacity of residual periportal hepatocytes to detoxify ammonia

Uses and Administration

Intravenous (IV) administration L Ornithine L Aspartate 5 g in 250 mL 0.9% sodium chloride were administered intravenously to 10 healthy, fasting subjects over 30 min and blood levels of L-ornithine were measured at the end of infusion and hourly up to 24 h after infusion. A biphasic pattern was observed with a fast distribution phase ($t_{½}$ 15–25 min) and a slower terminal elimination phase ($t_{½}$ 120–150 min). Peak levels of L-ornithine 30 min after the beginning of the infusion were nearly 10 times basal levels that fell to normal within 7 h. The median area under the curve (AUC) for L-ornithine was 1.390 mmol /h/L.

Pregnancy and breast-feeding:

Pregnancy

This medicine is not recommended for use in pregnant women unless necessary. All the risks and benefits should be discussed with the doctor before receiving/taking this medicine.

Breast-feeding

This medicine is not recommended for use in breastfeeding women unless absolutely necessary. All the risks and benefits should be discussed with the doctor before receiving/taking this medicine

There is not enough reliable information about the safety of taking ornithine if you are pregnant or breast-feeding. Stay on the safe side and avoid use.

Side effects

Major & minor side effects for L-Ornithine L-Aspartate

· Nausea and Vomiting

· Diarrhea

· Flatulence

· Stomach pain

· Pain in the limbs

· Allergic skin reaction

Dosage:-

Missed Dose

Since this medicine is usually administered by a qualified healthcare professional in the clinical/hospital setting, the likelihood of a missed dose is very low. Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose. Do not double your dose to make up for the missed one.

Overdose

Since this medicine is administered in the hospital or clinical setting by a qualified healthcare professional, the likelihood of an overdose is very low. However, Seek emergency medical treatment or contact the doctor in case of an overdose.

Storage: - Store Below 25° C in a cool & dry place Protected from Light.

Improper Storage may deteriorate the product

Medicine: - Keep out of reach of children.

Presentation: - Each pack contain 10 ml vial of L-Ornithine -L-Aspartate infusion in a pack

Manufactured by:

AMERICAN REMEDIES©
Care & Cure with Research

American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA

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For the use only of a registered medical practitioner or a hospital or a laboratory

℞ L-Ornithine L-Aspartate Infusion

AMERICAN
L-ORNICAN
Infusion

Infusion Concentrate for IV Slow Drips Infusion

Composition:-

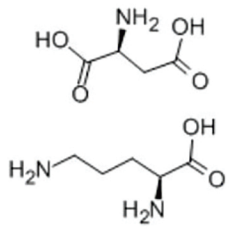
Each 10 ml Contains:-

L-Ornithine L Aspartate		5 g
Water for Injection	IP	q. s

Description

L-Ornithine L-aspartate (LOLA) is a mixture of two endogenous amino acids, L-ornithine and L-aspartate. LOLA is administered parenterally. The benefits of LOLA for the lowering of blood ammonia and consequently for the treatment of hepatic encephalopathy (HE) have been known for 50 years. Within that time, numerous randomized clinical trials and an associated meta-analysis have been performed to establish the efficacy of LOLA for the treatment of HE in cirrhosis.

L Ornithine L Aspartate is a White crystalline powder with the molecular formula $C_9H_{19}N_3O_6$ that is freely soluble in water and sparingly soluble in ethanol. LOLA is the stable salt of the naturally occurring amino acids, L-ornithine and L-aspartate is also available for injection as a 50% solution in 10.0 mL ampoules containing LOLA 5.0 g in water.



L-Ornithine L-aspartate

PHARMACOLOGY

Pharmacodynamics and Pharmacokinetics

L- Ornithine L Aspartate is a white crystalline powder with the molecular formula $C_9H_{19}N_3O_6$ that is freely soluble in water and sparingly soluble in ethanol. LOLA, the stable salt of the naturally occurring amino acids L-ornithine and L-aspartate, is available in as injection as a 50% solution in 10.0 mL ampoules containing LOLA 5.0 g in water. L Ornithine L Aspartate dissociates into its component amino acids L-ornithine and L-aspartate, which are absorbed from the small intestine by active transport across the brush border of the intestinal epithelium. This absorption is largely dependent on the sodium ion gradient. Aspartate is carried by the dicarboxylic amino acid transport system. In the mucosal cells, conversion of glutamine, glutamate, and aspartate to alanine, citrulline, ornithine, and proline occurs. Most of the aspartate undergoes transamination with pyruvate in the mucosal cells of the intestinal wall, forming alanine and oxaloacetate. This reaction sharply reduces the quantity of aspartate reaching the portal blood. In portal blood, most of the aspartate is found in the plasma with only a very small portion in erythrocytes. At concentrations of 1–25 mM, amino acid transporters are active just below their maximal turnover rates and net uptake via simple passive diffusion may exceed the rates via mediated pathways. In humans, normal concentrations range from 30 to 106 µ mol/L (mean 59.8) for L-ornithine and 0–24 µ mol/L (mean 7.5) for L-aspartate.

Intravenous Administration to Cirrhotic Patients

In a double-blind, randomized, placebo-controlled, cross-over clinical trial, 10 cirrhotic patients with HE and hyperammonemia were studied on four separate days with an interval of 2–5 days between single infusions of a range of doses of LOLA. After an overnight fast, the patients consumed a liquid protein formula of 0.25 g/kg at 9 a.m. and 0.50 g/kg at 1 p.m. Blood was drawn for analysis of ammonia and amino acids immediately before and every 2 h after infusion. Doses of LOLA were 0 g (vehicle only), 5 g, 20 g, and 40 g starting at 9 a.m. and continuing for 8 h. The dose of LOLA was selected randomly.

Following continuous infusion of placebo (0.9% NaCl), concentrations of L-ornithine and L-aspartate. remained stable for the entire 8-h period. Following LOLA 5 g (0.625 g/h), the concentration of L-ornithine increased to 132 ± 13 µ mol/L (4-h infusion) and 148 ± 10 µ mol/L (8-h infusion) while that of L-aspartate increased to a near steady state level (11 ± 2 µ mol/L after 4- to 8-h infusion). Continuous administration of 2.5 g/h LOLA (20 g/8 h) increased the level of L-ornithine and L-aspartate 4-fold whereas 5 g/h LOLA (40 g/8 h) led to a 10-fold increase of L-ornithine and a 20-fold increase of L-aspartate above basal placebo levels.

Excretion

L Ornithine L Aspartate is not excreted as such but urea, its major product, is excreted in the urine. Flux through the urea cycle is controlled by extracellular pH, primarily by bicarbonate and