

# L-GLUTAJECT®

L-Alanyl-L-Glutamine Infusion 20% w/v

50/100 ml

## Abridged Prescribing Information:

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**Presentation:** Each 100 ml contains, N (2)-L-alanyl-L-glutamine 20g, (8.20g L-alanine, 13.46g L-glutamine) and water for Injections I.P. q.s. **Indication:** As part of a clinical nutrition regimen in patients in hypercatabolic and/or hypermetabolic states. It should be given together with parenteral or enteral nutrition or a combination of both. **Dosage and administration:** Solutions of mixtures with an osmolality above 800 mosmol/l should be infused by the central venous route. **Adults:** The drug is administered in-parallel with parenteral nutrition or enteral nutrition or a combination of both. Dosage depends on the severity of the catabolic state and on amino acids/protein requirement. A maximum daily dosage of 2g amino acids and/or protein per kg body weight should not be exceeded in parenteral/enteral nutrition. The supply of alanine and glutamine via L-Alanyl-L-Glutamine should be taken into consideration in the calculation. The proportion of the amino acids supplied through L-Alanyl-L-Glutamine should not exceed approximately 30% of the total amino acids/protein supply. Daily dose 1.5 - 2.5 ml of L-Alanyl-L-Glutamine per kg body weight (equivalent to 0.3 - 0.5 g N(2)-L-alanyl-L-glutamine per kg body weight). This equates to 100 to 175 ml L-Alanyl-L-Glutamine for a patient of 70 kg body weight. Maximum daily dose: 2.5 ml equivalent to 0.5 g N(2)-L-alanyl-L-glutamine of L-Alanyl-L-Glutamine per kg body weight. The maximum daily dose of 0.5 g N(2) - L-alanyl-L-glutamine per kg body weight should be administered in combination with at least 1.0 g amino acids/protein, per kg body weight per day. With amino acids from L-Alanyl-L-Glutamine included, this results in a daily dosage of at least 1.5 g amino acids/protein per kg body weight. The following adjustments are examples for the supply with L-Alanyl-L-Glutamine and amino acids through the parenteral nutrition solution, and/or protein through enteral nutrition formula: Amino acids/protein requirement 1.2 g/kg body weight per day: 0.8 g amino acids/protein + 0.4 g N(2)-L-alanyl-L-glutamine per kg body weight. Amino acids/protein requirement 1.5 g/kg body weight per day: 1.0 g amino acids/protein + 0.5 g N(2)-L-alanyl-L-glutamine per kg body weight. Amino acids/protein requirement 2 g/kg body weight per day: 1.5 g amino acids/protein + 0.5 g N(2)-L-alanyl-L-glutamine per kg body weight. L-Alanyl-L-Glutamine is an infusion solution concentrate which is not designed for direct administration. Patients with total parenteral nutrition: The rate of infusion depends on that of the carrier solution and should not exceed 0.1 g amino acids/kg body weight per hour. L-Alanyl-L-Glutamine should be mixed with a compatible amino acid carrier solution or an amino acid containing infusion regimen prior to administration. Patients with total enteral nutrition L-Alanyl-L-Glutamine is continuously infused over 20-24 hours per day. For peripheral venous infusion, dilute L-Alanyl-L-Glutamine to an osmolality  $\leq$  800 mosmol/l (e.g. 100 ml L-Alanyl-L-Glutamine + 100 ml saline.) Patients with combined enteral and parenteral nutrition. The full daily dosage of L-Alanyl-L-Glutamine should be administered with the parenteral nutrition, i.e. mixed with a compatible amino acid solution or an amino acid containing infusion regimen prior to administration. The rate of infusion depends on that of the carrier solution and should be adjusted according to the proportions of parenteral and enteral nutrition. Duration of administration. The duration of use should not exceed 3 weeks. **Contraindications:** The drug should not be administered to patients with severe renal insufficiency (creatinine clearance  $<$  25 ml/minute), severe hepatic insufficiency, circulatory shock, hypoxia, multiple organ failure, severe metabolic acidosis or known hypersensitivity to the active substances or to any of the excipients. **Warnings & precautions:** For a safe administration the maximum dose of L-Alanyl-L-Glutamine should not exceed 2.5 ml (corresponding to 0.5 g N(2)-L-alanyl-L-glutamine) per kg body weight per day. It should only be used as part of clinical nutrition, and its dosage is limited by the amount of protein/amino acids provided by nutrition. Whenever the clinical condition does not allow nutrition (e.g., circulatory shock, hypoxia, unstable critically ill patients, severe metabolic acidosis) L-Alanyl-L-Glutamine should not be administered. Oral/enteral intake of glutamine-supplemented formulas in combination with parenteral nutrition should be taken into consideration for calculation of the prescribed dose of L-Alanyl-L-Glutamine. It is advisable to regularly monitor liver function parameters in patients with compensated hepatic insufficiency. As there is currently insufficient data on administration of L-Alanyl-L-Glutamine to pregnant women, nursing mothers and children, administration of the preparation in these patient groups is not recommended. Serum electrolytes, serum osmolality, water balance, acid-base status, creatinine clearance, urea, as well as liver function tests (alkaline phosphatase, ALT, AST) and possible symptoms of hyperammonaemia should be controlled. The generally accepted limit for peripheral infusion is about 800 mosmol/l. Experience with the use of L-Alanyl-L-Glutamine for longer periods than nine days is limited. **Pregnancy:** Due to lack of experience, L-Alanyl-L-Glutamine should not be administered during pregnancy and lactation. **Symptoms and treatment of overdosage:** None known when correctly administered. **Reporting of suspected adverse reactions:** chills, nausea and vomiting can occur when the infusion rate of L-Alanyl-L-Glutamine is exceeded. Infusion should be stopped immediately in this case. **Drug interaction:** No interactions are known. **Storage:** Cool place preferably below 25°C. Protect from light on removal from manufacturer's carton. Do not freeze. **Manufactured by:** Eurocrit Labs International Pvt. Ltd. **Marketed By:** Amneal Healthcare Pvt. Ltd. 9th Floor, 901 to 905, Iscon Elegance S. G. Highway, Ahmedabad 380015, Gujarat, INDIA.



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