

Repotyn®

5% Composite Amino Acid IV Infusion with
D-Sorbitol and Electrolytes

Description

Repotyn® is a sterile aqueous solution of crystalline Amino Acids and D-Sorbitol with electrolytes, which are necessary as the nitrogen sources for parenteral nutrition. Nitrogen is provided in the form of essential and non-essential amino acids. **Repotyn®** contains all 18 essential and non-essential amino acids needed for protein synthesis. The amino acid composition is such that positive nitrogen balance can be achieved in the postoperative period and during extended periods of intravenous nutrition. The solution is clear, colorless, having a pH lying in the range of 5.7 to 7.0.

Composition

Each 100 ml contains

| Active ingredients | Specifications | Quantity |
|----------------------------------|----------------|----------|
| Essential Amino Acids | | |
| L-Isoleucine | USP | 0.352 g |
| L-Leucine | USP | 0.490 g |
| L-Lysine Hydrochloride | USP | 0.430 g |
| L-Methionine | USP | 0.225 g |
| L-Phenylalanine | USP | 0.533 g |
| L-Threonine | USP | 0.250 g |
| L-Tryptophan | USP | 0.090 g |
| L-Valine | USP | 0.360 g |
| L-Histidine | USP | 0.250 g |
| L-Tyrosine | USP | 0.025 g |
| Non-Essential Amino Acids | | |
| L-Arginine | USP | 0.500 g |
| L-Aspartic Acid | USP | 0.250 g |
| L-Glutamic Acid | BP | 0.075 g |
| L-Alanine | USP | 0.200 g |
| L-Cystine | BP | 0.010 g |
| Glycine (Aminoacetic Acid) | USP | 0.760 g |
| L-Proline | USP | 0.100 g |
| L-Serine | USP | 0.100 g |
| Carbohydrate | | |
| D-Sorbitol BP | BP | 5.000 g |

Electrolytes (mmol/L)

| | | | |
|-------------------------------|------|---|------|
| Sodium (Na ⁺) | 35.5 | Chloride (Cl ⁻) | 53.4 |
| Potassium (K ⁺) | 25.0 | Acetate (CH ₃ COO ⁻) | 25.0 |
| Magnesium (Mg ⁺⁺) | 2.5 | | |

Indications

Repotyn[®] is indicated as a source of amino acids for protein synthesis in patients needing intravenous nutrition. **Repotyn**[®] is particularly suitable for patients with basal amino acid requirements. **Repotyn**[®] is also indicated in faster recovery in surgery, burns, renal insufficiency, hepatic insufficiency and effective management of cancer.

Dosage

Adults:

The nitrogen requirement for maintenance of body protein mass depends on the patient's condition (nutritional state and degree of metabolic stress). The requirements are 0.10-0.15g nitrogen/kg/day (no or minor metabolic stress and normal nutritional state), 0.15-0.20g nitrogen/kg/day (moderate metabolic stress with or without malnutrition) and up to 0.20-0.25g nitrogen/kg/day (severe catabolism as in burns, sepsis and trauma). The dosage range 0.10-0.25g nitrogen/kg/day corresponds to 15-35 ml **Repotyn**[®] /kg/day. In obese patients, the dose should be based on the estimated ideal weight. Depending upon patient's requirements, 1000-2000 ml **Repotyn**[®] may be infused intravenously per 24 hours. **Repotyn**[®] should be infused slowly, at rates 1.4-2.8 ml (30-60 drops) per minute.

Infants and children:

In children and infants, the recommended dose of **Repotyn**[®] is 28-35 ml/kg body weight/day, with a step wise increase in the rate of administration during the first week.

Use in Pregnancy

Successful and safe administration of amino acid solutions during pregnancy in the human has been reported. Animal reproduction studies have not been carried out with this preparation.

Side Effects

This preparation is usually well tolerated. Nausea occurs rarely. Vomiting, flushing and sweating have been observed during infusion of the solution at rates exceeding the recommended maximal rate. Transient increases in liver test during intravenous nutrition have been reported. The reasons are at present unclear. The underlying disease and the components and their amount in the intravenous feeding regimens have been suggested. Hypersensitivity reactions have been reported. As with all hypertonic infusion solution, thrombophlebitis may occur when peripheral veins are used. The incidence may be reduced by the simultaneous infusion of 10% fat emulsion. If given to severely ill, premature infants, hyperphenylalaninemia may occur.

Contraindications

This preparation is contraindicated in patients with inborn errors of amino acids metabolism, irreversible liver damage and severe uremia when dialysis facilities are not available. This preparation is also contraindicated in patients with known hypersensitivity to any of its ingredients.

Precautions

Hyperphenylalaninemia has been noted in severely ill, premature infants. In these patients, monitoring of the phenylalanine level is recommended and the infusion rate to be adjusted as needed. Do not use if the solution is turbid or contains particles. Discard any unused portion.

Drug Interactions

At the recommended dosage this solution have no pharmacological effect and is expected not to interact with other medicaments.

Compatibility

This solution should not be mixed with other preparations because of the increased risk of microbial contamination and incompatibility.

Pharmaceutical Precautions

Protect from light and store between 15°C to 25°C temperature. Avoid freezing. Keep out of the reach of children.

Commercial Pack

Repotyn[®] is available in 500 ml glass bottle.

® Registered Trade Mark



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