Repotyn® Max

7% Amino Acid IV Infusion with Electrolytes & 10% Glucose

Description

Repotyn® Max is a sterile aqueous solution of 7% amino acids IV infusion and 10% glucose 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® Max** 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.

Composition

Each 100 ml contains

Active ingredients	**Specification**	**Quantity**
L-Isoleucine	USP	0.39 g
L-Leucine	USP	0.53 g
L-Lysine Hydrochloride	USP	0.39 g
L-Methionine	USP	0.19 g
L-Phenylalanine	USP	0.55 g
L-Threonine	USP	0.30 g
L-Tryptophan	USP	0.10 g
L-Valine	USP	0.43 g
L-Histidine	USP	0.24 g
L-Tyrosine	USP	0.05 g
L-Arginine	USP	0.33 g
L-Aspartic Acid	USP	0.41 g
L-Glutamic Acid	BP	0.90 g
L-Alanine	USP	0.30 g
L-Cystine	BP	0.14 g
Glycine (Aminoacetic Acid)	USP	0.21 g
L-Proline	USP	0.81 g
L-Serine	USP	0.75 g

Carbohydrate

Anhydrous Glucose	BP	10.00 g

Electrolytes (mmol/L)

Sodium (Na^+)	50.0	Magnesium (Mg^{++})	1.5
Potassium (K^+)	20.0	Chloride (Cl^-)	32.0
Calcium (Ca^{++})	2.5		

Nitrogen content: 9.4 g/L

Energy content: 2.7 MJ (650 kcal)/L

Indications

Repotyn® Max is indicated as source of amino acids, glucose and electrolytes in adult and pediatric patients needing IV nutrition. **Repotyn® Max** is particularly suitable for patients with basal amino acids requirements.

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 11-27 ml **Repotyn® Max**/kg/day. In obese patients, the dose should be based on the estimated ideal weight. Depending upon patient's requirements, 1000-2000 ml **Repotyn® Max** may be infused intravenously per 24 hours. **Repotyn® Max** should be infused slowly; at a rate not exceeding 500 ml in 3 hours corresponding to approximately at rates 1.4-2.8 ml (30-60 drops) per minute.

Infants and children:

In infants & children, a maximal rate of infusion of 30 ml **Repotyn® Max**/kg body weight/day is recommended, with a step wise increase in the rate of administration during the first week of treatment.

Use in pregnancy

Successful and safe administration of amino acid solution during pregnancy in the human has been reported. Animal reproduction studies have not been carried out with 7% amino acid IV infusion with 10% glucose & electrolytes.

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.

Contraindications

This preparation is contraindicated in patients with inborn errors of amino acids metabolism, severe liver damage & severe uremia when dialysis facilities are not available. Due to the content of the glucose, this preparation is contraindicated in patients with hyperosmolar nonketotic diabetic coma. 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. This preparation should be used with caution in patients with diabetes mellitus, severe heart failure or with renal function in combination with fluid restriction or oliguria/anuria of other origin. In patient with hyperglycemia, administration of exogenous insulin might be necessary.

Do not use if the solution is turbid or contains particles. Discard any unused portion.

Drug interactions

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

Pharmaceutical precautions

Protect from light and store between 15^{o}C to 25^{o}C temperature. Avoid freezing. Keep away from the reach of children.

Commercial pack

Repotyn® Max is available in 500 ml glass bottle.

® Registered Trade Mark

Manufactured by
Popular Infusion Ltd.
For

ACI Limited
Narayanganj, Bangladesh