

Rx **AM-Amino T**TM **10%**

All Essential and Nonessential Pure Amino Acid for Intravenous Infusion (10%)

500 ml

Abridged Prescribing Information:

AM-Amino-TTM

All essential and Nonessential Pure Amino Acid for Infusion Intravenous (10%)

PRESENTATION: Each 100ml contains Amino Acid 10.09 g. List of excipients L-Aspartic Acid, L-Glutamic acid, L-Lysine Monoacetate, Eq. to L-Lysine, L-Arginine, L-Histidine, L-Phenylalanine, L-Tyrosine, L- Methionine, L- Cystine, L- Leucine, L- Isoleucine, L- Valine, L- Serine, L- Alanine, L- Threonine, L- Proline, L- Tryptophan, Glycine, Water for injection. **PHARMACEUTICAL FORM:** Intravenous Infusion, Clear, colorless injection. **INDICATIONS:** Used as a parenteral nutrition supplement in prophylaxis and therapy for protein deficiency, Pre and & post-operative conditions, Inadequate or impossible oral feeding, Stenosis in the GI tract, Inflammatory Bowel Disease and short gut syndrome, Chronic Diarrhea and Vomiting, Malabsorption syndrome, Sepsis, Diffuse peritonitis, Fistulas, Chylous ascites, malnutrition and clinical outcomes, Persistent pyrexial state, Nephrosis, amyloidosis, Immune compromised patients, HIV infection, Transplantation, cancer and related cachexia, burns, pregnancy, head injuries, prolonged coma. **DOSAGE AND ADMINISTRATION-Administration:** Daily dose 1.0 to 2.0gm of amino acid/kg BW. Max. Infusion rate 1.0 ml/kg BW/hr, Min. daily dose 2.0g amino acids/kg BW **Method of Administration Administered** via a central vein as a continuous infusion. **CONTRAINDICATIONS:** Disturbances of amino acids metabolism, metabolic acidosis, renal insufficiency without haemodialysis or hemofiltration treatment, advance liver insufficiency, fluid overload, shock, hypoxia, decompensated heart failure. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** Serum electrolytes, fluids balance and renal function should be monitored. Folic acid should be giving daily. Strict asepsis should be maintained. Use in Specific Populations: **Pregnancy:** Limited data; consider potential risks. **Lactation:** Unknown if excreted in human milk; consider benefits versus risks. **Pediatric Use:** Safety and efficacy not established. **Undesirable effects:** None known when correctly administered **Common:** Irritation of the vein wall (When infusion via peripheral veins. **Thrombophlebitis** **Overdose:** Shivering, vomiting, nausea. Increased renal amino acid losses can occur when Amino acid solution is given in overdose. **Pharmacodynamic Properties:** The amino acids contained in Amino acid infusion are all naturally occurring physiological compounds. **Pharmacokinetic Properties:** **Absorption:** Amino acids enter the plasma pool of corresponding free amino acids. **Distribution:** Interstitial fluids and into the intracellular space of different tissues. **Elimination:** Half-life is between 10-30 minutes. **Storage:** Store below 30°C. Protect from light on removal from the original carton. Do not freeze. **PACK SIZE:** In 100ml, 200ml and 500ml glass bottle. Before prescribing, please consult full prescribing information available from Amneal Healthcare Pvt. Ltd. 9th Floor, 901 to 905, Iscon Elegance, S. G. Highway, Ahmedabad 380015, Gujarat, India.



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