For the use of a registered medical practitioner or a Hospital or a Laboratory only

Amino Acids and Sorbitol injection with/without Electrolytes

NIRMIN®*

DESCRIPTION:

NIRMIN®* is a clear, colourless injection containing well-balanced mixture of pure crystalline, essential and non-essential amino acids, which is optimum
concentration for protein synthesis. The infusion is available in two formulations:
NIRMIN 5-S ™*–Amino acid 5% w/v + 5% w/v sorbitol
NIRMIN 10 Plus®* – Amino acid (10% w/v) injection with electrolytes.
The infusion could given either by peripheral or central route by suitable adjusting the flow rate.

COMPOSITION:

Each 100 mL contains:

	NIRMIN 5-S™*	**NIRMIN 10 Plus®***
L-Isoleucine USP	0.352 g	0.510 g
L- Leucine USP	0.490 g	0.890 g
L- Lycine HCl USP	0.430 g	0.700 g
L- Methionine USP	0.225 g	0.380 g
L- Phenylalanine USP	0.533 g	0.510 g
L- Threonine USP	0.250 g	0.410 g
L- Tryptophan USP	0.090 g	0.180 g
L- Valine USP	0.360 g	0.480 g
L- Arginine HCl USP	0.500 g	---
L- Arginine IP	---	0.920 g
L- Histidine USP	---	0.520 g
L- Histidine HCl H_2O BP	0.250 g	---
Glycine IP	0.760 g	0.790 g
L- Alanine USP	0.200 g	1.370 g
L- Proline USP	0.100 g	0.890 g
L- Aspartic Acid BP	0.250 g	0.130 g
L- Asparagine H_2O	---	0.372 g
L- Cysteine HCl H_2O USP	---	0.073 g
L- Cysteine BP	0.010 g	---
L- Glutamic Acid USP	0.075 g	0.460 g
L- Ornithine HCl	---	0.320 g
L- Serine USP	0.100 g	0.240 g
L- Tyrosine USP	0.025 g	0.030 g
Acetyl tyrosine BP	---	0.123 g
L- Malic Acid USP	---	0.100 g
Sodium Acetate $3H_2O$ IP	---	0.395 g
Potassium Acetate USP	---	0.245 g

Magnesium Acetate $4H_2O$ BP	---	0.056 g
Sodium Dihydrogen Phosphate $2H_2O$ IP	---	0.140 g
Water for Injections IP	q. s.	q. s.
Total Amino Acids	5.000 g	10.000 g
Sorbitol IP	5.000 g	---
Electrolytes mmol/L	---	---
Na^+ (mmol)	37.00	45.00
K^+ (mmol)	---	25.00
Mg^{2+} (mmol)	---	2.50
$Acetate^-$ (mmol)	---	59.00
Cl^- (mmol)	59.00	62.00
$H_2PO_4^-$ (mmol)	---	9.00
L-$Malate^{2-}$ (mmol)	---	7.50
Osmolarity (mOsmol/L)	800	1040
Total Energy (Kcal)	400 kcal/L	400 kcal/L
Non Protein Energy (Kcal)	200 kcal/L	---
Nitrogen (g)	7.25 g/L	16 g/L

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic

Pharmacotherapeutic group: Amino acids - solution for parenteral nutrition,

The amino acids contained in NIRMIN®* are all naturally occurring physiological compounds. As with the amino acids derived from the ingestion and assimilation of food proteins, parenterally administered amino acids enter the body pool of free amino acids and all subsequent metabolic pathways.

PHARMACOKINETIC PROPERTIES:

The amino acids in NIRMIN®* enter the plasma pool of corresponding free amino acids. From the intravascular space, amino acids distribute to the interstitial fluid and, are individually regulated for each single amino acid, into the intracellular space of different tissues as required.

Plasma and intracellular free amino acid concentrations are endogenously regulated within narrow ranges, depending on the age, nutritional status and pathological condition of the patient.

Balanced amino acid solutions such as NIRMIN®* do not significantly alter the physiological amino acid pool when infused at a constant and slow infusion rate.

Characteristic changes in the physiological amino acid pool of the plasma are only foreseeable when the regulative function of essential organs like liver and kidneys are seriously impaired. In such cases special formulated amino acid solutions may be recommended for restoring homeostasis.

Only a small proportion of the infused amino acids is eliminated by the kidneys. For the majority of amino acids plasma half-lives between 10 and 30 minutes have been reported.

INDICATIONS:

For supply of amino acids as part of a parenteral nutrition regimen.

Amino acid solutions should be administered generally in combination with adequate amount of energy Supplements.

NIRMIN®* is highly appreciated as a parenteral nutrition supplement in the following conditions.

- Prophylaxis and therapy for protein deficiency
- Pre & Post-Operative conditions

- Inadequate or impossible oral feeding
- Stenosis in the gastrointestinal tract
- Inflammatory Bowel Disease and short gut syndrome
- Chronic Diarrhoea and vomiting
- Malabsorption syndrome
- Sepsis
- Diffuse peritonitis
- Fistulas
- Chylous ascites
- Malnutrition and clinical outcomes
- Persistent pyrexial state
- Nephrosis, amyloidosis
- Immuno compromised patients
- HIV infections
- Transplantations
- Cancer and related cachexia
- Burns
- Pregnancy
- Head Injuries
- Prolonged coma

DOSAGE AND ADMINISTRATION:
Dosage depends on the severity of the catabolic state and on the amino acid requirement.

Recommended Dosage for NIRMIN 5-S™*
- Daily Dose: 0.8 to 1.0 g amino acids/kg BW
- Maximum Infusion rate: 2.0 ml/kg BW/hr (equivalent to 0.1 g Amino acid /kg BW /hr)
- Maximum daily dose: 1.0 g amino acids/kg BW
- For the administration via a peripheral or central vein as a continuous infusion.

Recommended Dosage for NIRMIN 10 Plus®*
- Daily Dose: 1.0 to 2.0 gm of amino acids/kg BW.
- Maximum Infusion rate: 1.0 ml/kg BW/hr (equivalent to 0.1 g Amino acid /kg BW /hr)
- Maximum daily dose: 2.0 g amino acids/kg BW
- For the administration via a central vein as a continuous infusion.

The solution is administered as long as a parenteral nutrition is required.
NIRMIN®* is contraindicated in children.

CONTRAINDICATION:
As for all amino acid solutions the administration of NIRMIN®* is contra-indicated in the following conditions:
Disturbances of amino acid metabolism, metabolic acidosis, renal insufficiency without haemodialysis or haemofiltration treatment, advanced liver insufficiency, fluid overload, shock, hypoxia, decompensated heart failure.
The administration of NIRMIN®* is contra-indicated in neonates.
For parenteral nutrition of infants and small children and children paediatric amino acid preparations should be used, which are formulated to meet the different metabolic needs of children.

No clinical studies have been conducted with NIRMIN®* solution in newborns, infants or children.

WARNING AND PRECAUTION:

Serum electrolytes, fluid balance and renal function should be monitored.

In cases of hypokalemia and/or hyponatremia adequate amounts of potassium and/or sodium should be supplied simultaneously.

Amino acid solutions may precipitate acute folate deficiency, folic acid should therefore be given daily.

Care should be exercised in the administration of large volume infusion fluids to patients with cardiac insufficiency.

The choice of a peripheral or central vein depends on the final osmolarity of the mixture. The general accepted limit for peripheral infusion is about 800 mosm/l, but it varies considerably with the age and the general condition of the patient and the characteristics of the peripheral veins.

Strict asepsis should be maintained, particularly when inserting a central vein catheter.

NIRMIN®* is applicable as part of a total parenteral nutrition regimen in combination with adequateamounts of energy supplements. (Carbohydrate solutions, fat emulsions), electrolytes, vitamins and trace elements.

DRUG INTERACTION:

No interactions are known to date.

Due to the increased risk of microbiological contamination and incompatibilities, amino acid solutions should not be mixed with other medicinal products.

FERTILITY, PREGNANCY AND LACTATION:

No specific studies have been performed to assess the safety of NIRMIN®* in pregnancy or lactation. However, clinical experiences with similar parenteral amino acid solutions have shown no evidence of risk during pregnancy or breastfeeding. The risk/benefit relationship should be considered before administering NIRMIN®* during pregnancy or breastfeeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Not relevant.

UNDESIRABLE EFFECT:

None known when correctly administered.

Those that occur during overdose (see below) are usually reversible and regress when therapy is discontinued. Infusion via peripheral veins in general can cause irritation of the vein wall and thrombophlebitis.

No clinical studies have been conducted.

OVERDOSE:

As with other amino acid solutions shivering, vomiting, nausea, and increased renal amino acid losses can occur when NIRMIN®* is given in overdose or the infusion rate is exceeded. Infusion should be stopped immediately in this case.

It may be possible to continue with a reduced dosage.

A too rapid infusion can cause fluid overload and electrolyte disturbances.

There is no specific antidote for overdose. Emergency procedures should be general supportive measures, with particular attention to respiratory and cardiovascular systems. Close biochemical monitoring would be essential and specific abnormalities treated appropriately

STORAGE:
Store below 25° C, Do not Freeze, Protect from Light.

PRESENTATION:
NIRMIN 5-S™* – In 100 mL, 200 mL, 500 mL and 1000 mL Glass Bottle.
NIRMIN 10 Plus®* - In 100 mL, 200 mL, 500 mL and 1000 mL Glass Bottle.

ACULIFE®
Manufactured in India by:
Aculife Healthcare Pvt. Ltd.
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* TM owners-Nirma Ltd.