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

AMINO ACIDS (5% w/v) AND SORBITOL (5% w/v) INTRAVENOUS INJECTION AND INTRAVENOUS FAT EMULSION (20%w/v)

NIRMIX®*

DESCRIPTION:

NIRMIX®* is a complete and convenient system of administrating nutrition. This system consists of NIRMIN 5-S™* 750 mL filled in 1 litre bottle and NIRPID 20%™* 250 mL supplied along with two-way spike and a dedicated I.V.set.

The two – way spike aids in the transfer of NIRPID®* solution into the 1 litre NIRMIN®* bottle in order to obtain a complete intravenous nutrition mix.
The two –way spike has 2 white spike with protective covers. This two-way spike is E.O. Sterilised

PHARMACOLOGY:

NIRPID®* is eliminated from the circulation via the same metabolic pathway as natural chylomicron, and is unutilized as a source of energy. NIRPID®* is rich in essential fatty acids & prevents essential fatty acid deficiency. NIRMIN®* contains all essential & non essential amino acids needed for protein synthesis.

COMPOSITION:

NIRMIN 5-S™*	
Composition:	
Each 100 mL contains:	
L-Isoleucine USP	0.352 g
L- Leucine USP	0.490 g
L- Lysine HCl 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- Arginine HCl USP	0.500 g
L- Histidine HCl H2O BP	0.250 g
Glycine IP	0.760 g
L- Alanine USP	0.200 g
L- Glutamic Acid USP	0.075 g
L- Aspartic Acid BP	0.250 g
L- Proline USP	0.100 g

L- Serine USP	0.100 g
L- Tyrosine USP	0.025 g
L-Cystine BP	0.010 g
Sorbitol IP	5.000 g
Water For Injections IP	q. s.
Electrolytes	mmol/lit
Na^+	37.00
Cl^-	59.00
Total Amino Acids	50.00 g/L
Total Energy	400 kcal/L
Non Protein Energy	200 kcal/L
Total Nitrogen content	7.25 g/L
Osmolarity (mOsmol/L)	800

NIRPID 20%™*

NIRPID®* is an intravenous fat emulsion and has the folliwing Composition Each 100 mL (of emulsion) Contains

Composition:	
Each 100 mL contains:	
Soyabean Oil IP	20.00 gm
Egg Lecithin	1.20 gm
Glycerol lP	2.25 gm
Water for Injections IP	q. s.
Energy Content	2000 Kcal/L
Osmolarity (mOsmol/L)	279

After mixing, 1000 ml of NIRMIX®* contains	
Amino Acids	37.50 g
Soybean Oil	50.00 g
Sorbitol	37.50 g
NA+	28.00 mmol/L
CI-	44.25 mmol/L
ph	5.0 to 7.0
Osmolarity	670 mOsmol/L

Each 1000 mL provides 5.43 g nitrogen and 650 Kcal of non-protein calories.

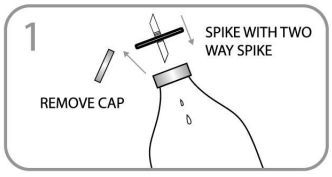
INDICATIONS:

- Short term parenteral nutrition via peripheral route.
- Pre & Post operative nutrition disturbances
- Cancer & associated cachexia
- Intravenous nutrition in burns
- G.I.Tract disease, Tumor, peritonitis, Ulcerative colitis, Fistula.
- Short bowel syndrome, inflammatory bowel disease.
- Malabsorption & malnutrition

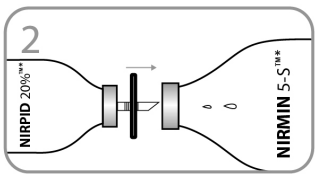
- Prolong unconsciousness
- Head injury,Poisoning

CONTRAINDICATIONS:
Disorder of fat metabolism, irreversible liver damage, acute shock, disorder of Amino acid metabolism, metabolic acidosis, renal insufficiency

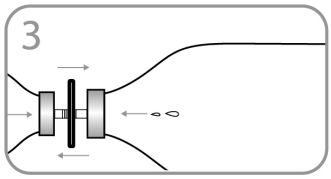
MIXING PROCEDURE:
NIRMIX®* Contains NIRMIN®* & NIRPID®* separately supplied along with two-way spike. These solutions must be mixed immediately prior to administration and the mix preparation of NIRMIX®* must be administered within 12 hours of mixing. No additives or electrolytes should be added to the mixed preparation. The order of mixing is important.



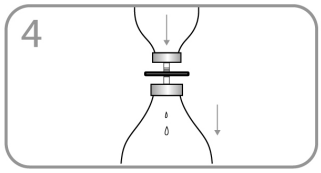
Open one end of the two way spike bottles with the spike and insert spike into NIRPID®* bottle.



Now open the other end of the Two-way spike and of the two –way spike and insert spike into the NIRMIN 5-S™* Bottle, Keeping the bottle in a horizontal position.



After connecting the two bottles with the spike, Bottles should be shaken slowly, keeping them in horizontal position.



Slowly invert the NIRPID®* bottle vertically above the NIRMIN 5-S™* bottle. Keeping the two-way spike in place. Maintain this position till all the NIRPID®* solution is emptied in the NIRMIN®* bottle and the two –way spike. Insert spike into the 1litre bottle using an I.V. set supplied with this pack. NIRMIX®* solution is now ready for infusion.

DOSAGE:
1-2 liters NIRMIX®* can be infused over 12-24 hours according to the requirement of energy and nitrogen of the patient.

INFUSION RATE:
The recommended rate of infusion is 0.5 ml/min for initial 10 minutes. If no adverse reactions occur, the rest of the infusion must be given over at least 5-6 hours at an infusion rate of 3ml per minutes. NIRMIX®* must be administered by slow intravenous infusion via either a peripheral or central vein.

SIDE EFFECTS:
In case of nausea, Shivering Chills & rise of temperature, the infusion of NIRMIX®* should be discontinued. Vomiting, Flushing, Sweating may occur if recommended infusion rate is not allowed.

PRECAUTION:
Fat level in blood should be checked prior to infusing NIRMIX®* bottle. Discard all unused contents.

USE IN PEDIATRICS:
NIRMIX®* is not recommended for use in infants and children as well as in early pregnant & lactating mothers.

STORAGE:
NIRMIX®*should be stored below 25° C. Do not freeze. Protect from the light.

SHELF LIFE:
NIRMIX®* should be used within 24 months from the date of manufacturing. NIRMIX®* must be used within 12 hours after mixing.

ACULIFE®
Manufactured in India by:
Aculife Healthcare Pvt. Ltd.
Sachana, Gujarat 382150, India.
* TM owners-Nirma Ltd.