For the use of Registered Medical Practitioner or Hospital or a Laboratory only

Dextran 40(10% W/V) Injection IP in Sodium Chloride Injection 0.9% w/v And Dextrose Injection 5% w/v

NIRTRAN®* 40

In NS & 5D

COMPOSITION:

NIRTRAN 40 NS™* Each 100 mL Contain	
Dextran 40 For Injection Bp	10.0 gm
Sodium Chloride IP	0.9 gm
Water For injection IP	q.s.
mOsmol/L	311
mEq/L	NA^+150
	CL^-150

NIRTRAN 40 5D™* Each 100 mL Contain	
Dextran 40 For Injection Bp	10.0 gm
Dextrose IP eq. to Dextrose anhydrous	5.0 gm
Water For injection IP	q.s.
mOsmol/L	280

CLINICAL PHARMACOLOGY:

NIRTRAN®*40 is a sterile solution in sodium chloride Injection or in dextrose Injection, of dextran of average molecular wt. of about 40,000 Dalton (range 20,000 to 2,00,000) derived from fermentation of sucrose by means of a certain strain of Leuconostoc mesentererioides (NCTC 10817)

PHARMACOKINETICS:

After intravenous infusion, NIRTRAN®*40 is evenly distributed in the vascular system. The kidney excretes the dextran of smaller molecular weight. Approximately 50% is lost within 6 hrs and 75% within 24 hrs. The remaining 25% is partly hydrolyzed and excreted in the urine, partly excreted in the urine, partly hydrolyzed and excreted in the faces and partly oxidized. The unexcreted dextran molecules lie in extracellular fluid and are temporarily taken up by the reticuloendothelial system. The unexcreted NIRTRAN®*40 is slowly oxidized over a period of few weeks. The persistence as NIRTRAN®*40 is slowly oxidized over a period of few weeks. The persistence as NIRTRAN®*40 and its ultimate metabolic disposal are desirable feature of plasma volume expander.

INDICATION:

NIRTRAN®*40 has unique haemodynamic action:

- Plasma volume Expansion
- Thromboprophylaxis
- Improve Microcirculation

  There are variety of indication where therapy finds its applications of NIRTRAN-40
- Severe burns, Traumatic shock
- Pancreatitis
- Peritonitis
- Vascular surgery
- Sepsis
- Intra surgery & post-surgery
- Epidemic Hemorrhagic Fever

CONTRAINDICATIONS:

Known Hypersensitivity to dextran
Marked hemorrhagic tendencies e.g. thrombocytopenia
Manifest renal diseases, oliguria, and anuria
Pronounced heart failure

ADVERSE REACTIONS:

In rate situations, hypersensitivity reaction may occur ranging from mild flushing, urticaria and chills to more serious reaction involving hypotension and circulatory collapse. In case of any such anaphylactic reaction, infusion should be stopped immediately. If necessary, the patient's oxygenation should be increase and a suitable parenteral therapy may be initiated as:

(1) Adrenaline 0.05- 0.1 mg to be administration intravenously. According to patient's reaction and condition such dose should be administered repeatedly at intervals of 1-2 minutes.
(2) Corticosteroids e.g. prednisolone in the dose of 250-1000 mg administered intravenously.
(3) 5% Albumin solution as an alternative, Acetated Ringer's solution or lactated Ringer's solution as volume substitute.
(4) Antihistaminics to be administered only in severe reactions.

PRECAUTIONS:

(1) NIRTRAN®*40 should be injected very carefully in patients with cardiac insufficiency, polythemia etc.
(2) Any existing dehydration should be corrected prior to administration of product. Blood crossmatching procedure using enzyme may give misguiding result. Other procedure remains unaffected. Hence, laboratory should be informed to employ adequate techniques. A thorough saline wash may be conducted prior to process.
(3) Risk of fluid overload must be constantly borne reaction.

USE IN PREGNANCY:
In pregnant women, NIRTRAN®*40 should be administered in case of absolute need only and under the physician's direct control. NIRTRAN®*40 should be avoided in nursing women

DOSAGE & ADMINISTRATION:
Shock: A suggested dose of 500 ml NIRTRAN®*40 by rapid I.V. infusion followed by a further 500-1000 ml over the next 3-5 hours, patient with burns and major trauma require high doses.
Thromboembolic disorder: A suggested regimen of 500-1000 ml over 4-6 hrs on first day, then 500 ml over 4-6 hrs on the next and subsequent alternate days for not more than 10 days.
Surgery: 500 ml NIRTRAN®*40 before surgery daily for at least 3days. Post-operatively 500 ml should be administration on alternate days for not more than 10 days.
Peripheral vascular disorder: 500 ml NIRTRAN®*40 to be given every 12 hours for 4 days & repeated as require every 3-6 months.
Epidemic hemorrhagic fever: 200-300 ml NIRTRAN®*40 should be rapidly infused at the rate of 5-15 ml/min. or infused under pressure. Therefore dose should be decided depending on the clinical condition of patient.
A maximum recommended dose is 20-ml/kg body wt. during first 24 hrs. Doses of 10 ml/kg may be given daily thereafter for up to five days.

STORAGE:
Store at temperatures not exceeding 30° C. Avoid undue fluctuations of temperature.

PRESENTATION:
NIRTRAN®* 40 (In NS & 5D) 500 mL FFS Plastic container

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