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

HESTAR-200™

PENTASTARCH 3%, 6% & 10%

Hydroxyethyl Starch (200/0.5) 3%, 6% & 10% w/v
isotonic with Sodium Chloride
Intravenous Infusion

COMPOSITION

Each 100 ml contains :	HESTAR-200™ 3%	HESTAR-200™ 6%	HESTAR-200™ 10%
Hydroxyethyl Starch (200/0.5)	3.0 g	6.0 g	10.0 g
Sodium Chloride BP	0.9 g	0.9 g	0.9 g
Water for Injections BP	q.s.	q.s.	q.s.
Average Molecular Weight	2,00,000	2,00,000	2,00,000
Degree of Substitution	~0.50	~0.50	~0.50
mOsmol/L	308	308	308
mmol/L	Na^+ 154 Cl^- 154	Na^+ 154 Cl^- 154	Na^+ 154 Cl^- 154

CLINICAL PHARMACOLOGY

Hydroxyethyl Starch (HES) is an artificial colloid obtained from starch. It is composed almost exclusively of amylopectin, which is the highly branched and more stable component of starch. Plasma volume expansion of about 100% of the infused volume takes place over 4-8 hours (in **HESTAR-200™ 10%**) & 3-4 hours (in **HESTAR-200™ 6%**) in hypovolaemic patients. In case of **HESTAR-200™ 3%**, initially plasma volume expansion of 62% of the infused volume is obtained. **HESTAR-200™** leads to an improvement of blood circulation & microcirculation according their strengths, as per following:

Strength	Plasma volume expansion period
HESTAR-200™ 3%	1 - 2.5 hours
HESTAR-200™ 6%	3 - 4 hours
HESTAR-200™ 10%	4 - 8 hours

PHARMACOKINETICS

Hydroxyethyl Starch molecule is degraded by alpha amylase in serum and tissues into smaller fraction. The cleavage by amylase occurs at 1,4 glycosidic linkage. It is excreted mainly through kidney. About 47% appear within 24 hours in urine & only 10% is detectable in the plasma at this time in case of 6% & 10%. In case of 3% after 3 hours approximately 50% is detected and after 24 hours, only 9% is detected in the circulation. An addition of Hydroxyethyl Starch to whole blood increases the erythrocyte sedimentation rate; therefore, it is also used to improve the efficiency of granulocyte collection by centrifugal means.

INDICATIONS

- Prophylaxis and treatment of hypovolemia & shock due to
  (a) Surgery (b) Trauma (c) Burns (d) Infections
- Therapeutic Hemodilution
- Cardiac priming
- Therapeutic plasma exchange
- Preloading in spinal anaesthesia
- Acute Normovolemic hemodilution (autologous blood transfusion)

CONTRAINDICATIONS

- Severe haemorrhagic defects
- Renal failure with oliguria and anuria
- Hyperhydration states
- Severe congestive cardiac failure
- Patients allergic to starch

ADVERSE REACTIONS

- **Hypersensitivity :** such as rash or pruritis occurs, the administration should be discontinued or proper treatment should be given.
- **Haematologic :** if prolongation of bleeding tendency occurs, the administration should be discontinued or proper treatment should be given.
- **Gastrointestinal :** nausea and vomiting occur rarely.

PRECAUTIONS

- General precautions: Observe carefully blood viscosity, acid-base equivalence and electrolyte balance of patient.
- Since HESTAR may increase the renal toxicity of amino sugar antibiotics such as kanamycin, aminodeoxy kanamycin, gentamycin and paramomycin having a possibility of causing renal disturbances, the concomitant use with these antibiotics should be avoided.
- The interfering action of blood typing and cross matching has not been reported. However, it is recommended that these tests should be performed, before the administration of this product, if they are necessary.
- Since rapid infusion of HESTAR may cause circulatory disturbances and subsequent damage to the tissues, it is recommended to administer 500 ml of HESTAR for adult and 10 ml / kg of body weight for children by drip intravenous infusion over 30 min.
- Do not mix with citrated blood or an oily suspension preparation for injection.

USE IN PREGNANCY

HESTAR-200™ should not be used during early pregnancy, unless the benefits outweigh the hazards to the foetus.

DOSAGE AND ADMINISTRATION

In the light of possible anaphylactic reactions initially 10-20 ml **HESTAR-200™** is to be infused slowly, keeping the patient under close observation. The risk of a circulatory overload resulting from a too rapid and too high dosage must be taken into account. Special caution is recommended in patients with disturbed coagulation, heart failure and pulmonary oedemas, renal insufficiency and chronic hepatic diseases. The daily dose and rate of infusion are to be determined according to blood loss and hemodilution effects. In younger patients without cardiovascular or pulmonary risks a hematocrit value of 30% is regarded to be threshold for the use of colloidal volume substitutes.

Recommended daily dosage : For the therapy and prophylaxis of volume deficiency and shock (volume substitution therapy)

HESTAR-200™	Dose
3%	Up to 66 ml/kg body weight / hour
6%	Up to 33 ml/kg body weight / hour
10%	Up to 20 ml/kg body weight / hour

DOSAGE

500 to 1000 ml/day

RATE OF INFUSION

- **In haemorrhagic shock :** Up to 20 ml / kg body weight / hour (0.33 ml / kg / min)
- **In septic and burn shock:** Rate of infusion must be lowered
- **In children under 10 years of age:** Do not exceed 15 ml / kg body weight / hour
- **Hemodilution:** 500 ml in 4 - 6 hours, 2 X 500 ml in 8 - 12 hours.

STORAGE

Store below 25° C. Do not freeze. Protect from light.

PRESENTATION

HESTAR-200™ is available as **3%, 6%** & **10%** w/v Hydroxyethyl Starch with Sodium Chloride Intravenous Infusion in 500 ml plastic container.

Manufactured by :
Claris
Claris Lifesciences Limited
Chacharwadi-Vasana, Ahmedabad-382 213, India.

IEEC/HESTAR 200/00/E-1