

Data Sheet

STARQUIN[®] 200 10%

Presentation

STARQUIN 200 is a sterile injection containing 10% pentastarch in 0.9% sodium chloride injection. It is a clear, pale yellow to amber solution.

Each 100 mL of solution contains:

Pentastarch 10 g

Sodium Chloride BP 0.9 g

Water for Injection BP q.s to 100 ml

pH adjusted with Sodium Hydroxide BP

Concentration of Electrolytes:

Sodium 150 mmol

Chloride 150 mmol

pH approximately 5.0 (3-5-7.0)

Calculated osmolarity 310 mOsmol/litre

Uses

Actions

Pentastarch is a colloid synthesized from a waxy starch composed almost entirely of amylopectin. Hydroxyethyl ether groups are added to the glucose units of the starch and the resultant material is hydrolyzed to yield a product with a molecular weight suitable for use as a plasma volume expander and erythrocyte sedimenting agent. Pentastarch is characterized by its molar substitution and by its molecular weight. The molar substitution is 0.5 which means pentastarch has 50 hydroxyethyl groups for every 100 glucose units. The average molecular weight is approximately 200,000 with 90% of the polymers falling between the range of 15,000 and 600,000. Hydroxyethyl groups are attached by ether linkages at the C₂ and C₆ positions on the glucose molecule. The C₂/C₆ ratio is within the range 5.0 – 7.0/1.

Intravenous infusion of STARQUIN 200 10% injection results in a plasma expansion approximately 1.5 times greater than the infused volume due to influx of interstitial fluid in the intravascular space. The plasma volume expansion resulting from intravenous infusion of STARQUIN 200 10% injection persists for approximately 12 hours. The degree of plasma volume expansion and improvement in hemodynamic state depends upon the patient's intravascular status.

Pharmacokinetics

Pentastarch molecules below 50,000 are rapidly eliminated by renal excretion. A single dose of approximately 500 mL of STARQUIN 200 10% injection results in elimination in the urine of approximately 70% of the dose within 24 hours. The hydroxyethyl group is not cleaved by the body, but remains intact and attached to glucose units when excreted. Significant quantities of glucose are not produced as hydroxyethylation prevents complete metabolism of the smaller polymer.

STARQUIN 200 10% injection can be used to improve the efficiency of granulocyte collection by centrifugal means.

Indications

STARQUIN 200 injection is indicated in the treatment of hypovolemia when plasma volume expansion is desired. It is not a substitute for blood or plasma.

The adjunctive use of STARQUIN 200 10% injection in leukapheresis has also been shown to be safe and efficacious in improving the harvesting and increasing the yield of granulocytes by centrifugal means.

Dosage and administration

Dosage for Acute Use in Plasma Volume Expansion:

STARQUIN 200 10% injection is administered by intravenous infusion only. Total dosage and rate of infusion depends upon the amount of blood plasma lost and the resultant hemoconcentration. The maximum dose of pentastarch is 2 g/kg bodyweight/day equivalent to 20 mL/kg or approximately 3 bags of STARQUIN 200 in a 70 kg adult. Use beyond 72 hours has not been studied.

Dosage in Leukapheresis:

250 to 700 mL of STARQUIN 200 10% injection to which citrate anticoagulant has been added is typically administered by aseptic addition to the input line of the centrifugation apparatus at a ratio of 1:8 to 1:13 to venous whole blood. The STARQUIN 200 10% injection and citrate should be thoroughly mixed to assure effective anticoagulation of blood as it flows through the leukapheresis machine.

Administration Directions

CAUTION: Do not use plastic container in series connection. If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry to minimise the risk of air embolism. It is recommended that the intravenous administration set be replaced at least once every 24 hours.

To open, tear over wrap downwards at notch and remove solution container. Check for minute leaks by squeezing solution container firmly. Carefully inspect the solution in good light for cloudiness, particulate matter or leaks. Use only if solution is clear and container is intact.

Remove plastic protector from sterile set port at bottom of container. Attach administration set. Refer to complete directions accompanying set.

Monitor patients for possible anaphylactic reactions; refer warnings and precautions.

Contraindications

STARQUIN 200 10% injection is contraindicated in patients with known hypersensitivity to hydroxyethyl starch, hypervolaemia, hyperhydration, hypernatraemia, bleeding disorders, chronic liver disease and congestive heart failure where volume overload is a potential problem. STARQUIN 200 10% injection should not be used in renal disease with oliguria or anuria not related to hypovolemia. STARQUIN 200 10% injection should not be used in patients with acute cerebral infarction where cerebral oedema is a potential problem.

Warnings and precautions

As with all colloidal plasma volume substitutes, allergic (anaphylactic) reactions of varying severity may occur after infusion of STARQUIN 200, but such reactions are rare (less than 0.1%). Patients receiving STARQUIN 200 must be closely monitored for such reactions, which manifest as cutaneous eruptions or sudden flushing of the face and neck. Rarely, they may produce a drop in blood pressure, shock, cardiac and respiratory arrest. If an anaphylactic reaction occurs, immediately discontinue the infusion. Treat as required with oxygen and adrenaline (up to 5 µg/kg, repeated as required). Additional measures that may be useful,

include beta-2 adrenergic agonists for bronchospasm, IV antihistamines and corticosteroids. Tracheal intubation should not be delayed if upper airway obstruction is progressive. Monitor EEG and pulse oximetry if possible. All patients who have suffered an anaphylactic reaction must be admitted to hospital. Patients who remain clinically unstable after initial resuscitation should be admitted to an intensive care unit.

Use in Plasma Volume Expansion

Large volumes may alter the coagulation mechanism. Thus, administration of STARQUIN 200 10% injection may result in transient prolongation of prothrombin, partial thromboplastin and clotting times. With administration of large doses, the physician should also be alert to the possibility of transient prolongation of bleeding time.

Hematocrit may be decreased and plasma proteins diluted excessively by administration of large volumes of STARQUIN 200 10% injection. Administration of packed red cells, platelets, and fresh frozen plasma should be considered if excessive dilution occurs.

Use over extended periods

STARQUIN 200 10% injection has not been adequately evaluated to establish its safety in situations other than leukapheresis that require frequent use of colloidal solutions over extended periods.

Use in Leukapheresis

Slight declines in platelet count and haemoglobin levels may occur in donors undergoing repeated leukapheresis procedures using STARQUIN 200 10% injection, due to the volume expanding effects and to the collection of platelets and erythrocytes⁷. Hemoglobin levels usually return to normal within 24 hours. Hemodilution by STARQUIN 200 10% injection may also result in 24 hour declines of total protein, albumin, calcium and fibrinogen values. None of these decreases are to a degree recognized to be clinically significant risks to healthy donors.

Regular and frequent clinical evaluation and complete blood counts (CBC) are necessary for proper monitoring of STARQUIN 200 10% injection use during leukapheresis. If the frequency of leukapheresis is to exceed the guidelines for whole blood donation, you may wish to consider the following additional studies: total leukocyte and platelet counts, leukocyte differential count, hemoglobin and hematocrit, prothrombin time (PT), and partial thromboplastin time (PTT) tests.

General

The possibility of circulatory overload should be kept in mind. Caution should be used when the risk of pulmonary oedema and/or congestive heart failure is increased. Special care should be exercised in patients who have impaired renal clearance since this is the principal way in which pentastarch is eliminated.

Slightly raised indirect bilirubin levels may occur very rarely. Therefore, STARQUIN 200 10% injection should be used with caution in patients with a history of liver disease.

Elevated serum amylase levels may be observed temporarily following administration of STARQUIN 200 10% injection, although no association with pancreatitis has been demonstrated.

Carcinogenesis, Mutagenesis,

Long-term studies of animals have not been performed to evaluate the carcinogenic potential of STARQUIN 200 6%.

Use in pregnancy

Animal reproduction studies have not been conducted with STARQUIN 200 10% injection and it is also not known whether it can cause foetal harm or affect reproductive capacity when administered during pregnancy. STARQUIN 200 10% injection should be given during pregnancy only if clearly needed.

Use during lactation

It is not known whether pentastarch is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when STARQUIN 200 10% injection is administered to a nursing woman.

Effect on ability to drive and use machinery

STARQUIN 200 10% is unlikely to affect the ability to drive or use machinery.

Use in children

The safety and efficacy of STARQUIN 200 10% injection in children has not been established.

Adverse effects

The following have been reported: vomiting, fever, chills, pruritus, submaxillary and parotid glandular enlargement, mild influenza-like symptoms, headaches, muscle pains, peripheral oedema of the lower extremities, anaphylactoid reactions (periorbital oedema, urticaria wheezing – refer warnings and precautions), bleeding due to hemodilution, circulatory overload and pulmonary oedema.

Interactions

The safety and compatibility of other additives, other than citrate anticoagulant, have not been established.

Overdosage

See adverse effects.

Pharmaceutical precautions

Avoid excessive heat. Protect from freezing.

Product has a shelf life of 36 months from date of manufacture. Once opened, use within 24 hours. If only part used, remainder must be discarded. It is recommended that the product be stored between the range of 15° - 25°C, however, brief exposure up to 40°C does not adversely affect the product.

Medicine Classification

General sale medicine.

Package quantities

STARQUIN 200 10% injection is supplied sterile and non-pyrogenic in 500 mL EXCEL® flexible infusion containers. These containers are packaged 24 units per case.

Name and Address

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