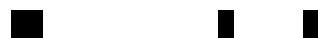




3054756



3054756 (Rev. February 2019)

Plasmanate®

Plasma Protein Fraction (Human) 5%, USP

DESCRIPTION

This product has been prepared from large pools of human plasma. Each 100 mL of Plasma Protein Fraction (Human) 5%, USP—Plasmanate® contains 5 g selected plasma proteins buffered with sodium carbonate and stabilized with 0.004 M sodium caprylate and 0.004 M acetylthiophan. The plasma proteins consist of approximately 88% normal human albumin, 12% alpha beta globulins and not more than 1% gamma globulin as determined by electrophoresis.(1) The concentration of these proteins is such that this solution is iso-oncotic with normal human plasma and is isotonic. The approximate concentrations of the significant electrolytes in Plasmanate are sodium 145 mEq/L, potassium 0.25 mEq/L, and chloride 100 mEq/L. Plasmanate is clear amber colored. Plasmanate must be administered intravenously.

This product is designed to bring to the medical profession a preparation derived from human blood and similar to human plasma. Each vial of Plasmanate is sterile and heat-treated at 60°C for 10 hours against the possibility of transmitting the hepatitis viruses.



The blood group agglutinins and agglutinogens A and B are at such a low level in Plasmanate solution that its use has no effect on routine blood typing procedures. No chemical or microscopic alterations of the urine have been observed with its use.

Additionally, the manufacturing process was investigated for its capacity to decrease the infectivity of an experimental agent of transmissible spongiform encephalopathy (TSE), considered a model for the variant Creutzfeldt-Jakob disease (vCJD) and Creutzfeldt-Jakob disease (CJD) agents.(5-8) The production steps from Pooled Plasma to Effluent IV-1 in the Plasmanate manufacturing process have been shown to decrease TSE infectivity of that experimental model agent (a total of ≥ 7.0 logs). These studies provide reasonable assurance that low levels of vCJD/CJD agent infectivity, if present in the starting material, would be removed.

CLINICAL PHARMACOLOGY

In normal human volunteers, Plasmanate has resulted in an increased blood volume which lasted up to 48 hours.(2) Clinical experience has indicated that it is an adequate replacement for human plasma in the treatment of shock and is a suitable means of providing human proteins and their osmotic effect.

INDICATIONS AND USAGE

Solutions which are turbid or which have been frozen should not be used. Do not use if turbid. Do not begin administration more than 4 hours after the container has been entered. Partially used vials must be discarded. Vials which are cracked or which have been previously entered and damaged should not be used, as this may have allowed the entry of microorganisms. Plasmanate Protein Fraction (Human) 5%, USP—Plasmanate® contains no preservative.

PRECAUTIONS

General

Rapid infusion of Plasmanate (greater than 10mL/minute) has produced hypotension in patients undergoing surgery or in the preoperative or postoperative period. Blood pressure should be monitored during use and infusion slowed or ceased if sudden hypotension occurs.

Plasmanate does not provide coagulation factors and therefore does not correct coagulation disorders.

Drug Interactions

Plasmanate is compatible with whole blood, packed red cells as well as the standard carbohydrate and electrolyte solutions intended for intravenous use. It should, however, not be mixed with protein hydrolysates or solutions containing alcohol.

Pregnancy Category C

Animal reproduction studies have not been conducted with Plasmanate. It is also not known whether Plasmanate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Plasmanate should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Hypotension may occur, particularly following rapid infusion or intraarterial administration in patients on cardiopulmonary bypass. The blood pressure may normalize spontaneously after slowing or discontinuation of the infusion. Vasopressors will also correct the hypotension.

Flushing, urticaria, back pain, nausea and headache have been occasionally reported in conscious patients.

DOSAGE AND ADMINISTRATION

Dosage is based almost entirely on the nature of the individual case and response to therapy. The usual minimum effective dose in adults is 250–500 mL. As with any plasma expander, the dose should be adjusted or slowed according to the clinical response and rising blood pressure.

Administration should be by vein and preferably through an area of skin at some distance from the site of infection or trauma. Plasmanate is compatible with the usual carbohydrate and electrolyte solutions.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Only 16 gauge needles or dispensing pins should be used with 20 mL vial sizes and larger. Needles or dispensing pins should only be inserted within the stopper area delineated by the raised ring. The stopper should be penetrated perpendicular to the plane of the stopper within the ring.

A number of factors beyond our control could reduce the efficacy of this product or even result in an ill effect following its use. These include improper storage and handling of the product after it leaves our hands, diagnosis, dosage, method of administration, and biological differences among individual patients. Because of these factors, it is important that this product be stored properly and that the directions be followed carefully during use.



HOW SUPPLIED

Plasmanate is available in a 250 mL rubber-stoppered vial. Each single dose vial contains plasma protein in the following approximate amounts:

Size	Grams Protein
250 mL	12.5

STORAGE

Store at room temperature not exceeding 30°C (86°F). Solution that has been frozen should not be used. Do not use after expiration date.

REFERENCES

1. Hink JH Jr, Hidalgo J, Seeberg VP, Johnson FF. Preparation and properties of a heat-treated human plasma protein fraction. *Vox Sang.* 1957;2:174–86.
2. Bertrand JJ, Feichtmeir TV, Kolomeyer N, Beatty JO, Murphy PL, Waldschmidt WD, et al. Clinical investigations with a heat-treated plasma protein fraction—Plasmanate®. *Vox Sang.* 1959;4:399–402.