

**Table 1. Hydroxyethyl Starch Products Comparison
(Plasma Volume Expanders)**

| I. Formulation data | | |
|--|--|---|
| Attributes | Voluven® by Fresenius Kabi | Pentaspán™ by Bristol-Myers Squibb |
| Source | Artificial colloid derived from amylopectine. | Artificial colloid derived from amylopectine. |
| Composition | 6% hydroxyethyl starch (HES 130/0.4) in 0.9% sodium chloride. | 10% pentastarch in 0.9% sodium chloride. |
| Colour | Clear and colorless solution. | Clear, pale yellow to amber solution. |
| Average molecular weight | 100-150 kDa (mean 130 kDa) | 200-300 kDa |
| pH | 4.0 - 5.5 | Approximately 5.0 |
| Degree (ratio) of substitution of hydroxyethyl groups to glucose units | 0.38 - 0.45 | 0.40 - 0.50 |
| C ₂ /C ₆ ratio | 9:1 | Hydroxyethyl groups are attached primarily at C ₂ of the glucose unit and to a lesser extent at C ₃ and C ₆ (unspecified ratio). |
| Theoretical osmolarity (Normal plasma osmolarity approx. 280-300 mOsM) | 308 mOsM | Approximately 326 mOsM |
| Package type | Sterile and pyrogen free 250 and 500 mL plastic polyolefine bags (freeflex) with overwrap. | Sterile and nonpyrogenic 250 and 500 mL plastic bags. |
| Package size | In boxes of identical dimension: 30 x 250 mL; 20 x 500 mL | In boxes of identical dimension: 10 x 250 mL; 10 x 500 mL (as shipped-not in Product Monograph) |
| Storage conditions | Store at 15-25°C | Store at 15-25°C |

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| II. Medical/Clinical Information | | |
|---|--|--|
| Attributes | Voluven® by Fresenius Kabi | Pentaspán™ by Bristol-Myers Squibb |
| Indications for use | For the treatment of hypovolemia when plasma volume expansion is required. It is not a substitute for red blood cells or coagulation factors in plasma. | When plasma volume expansion is desired as an adjunct in the management of shock due to hemorrhage, surgery, sepsis, burns or other trauma. It is not a substitute for red blood cells or coagulation factors in plasma. |
| Contraindications | <ul style="list-style-type: none"> • Intracranial bleeding • Hyperhydration (especially in case of pulmonary oedema and congestive cardiac failure) • Renal failure with oliguria or anuria not related to hypovolemia • Dialysis treatment • Severe hypernatremia or hyperchloremia • Known hypersensitivity to hydroxyethyl starch | <ul style="list-style-type: none"> • Bleeding disorders • Congestive heart failure where volume overload is a potential problem • Renal disease with oliguria or anuria not related to hypovolemia • Known hypersensitivity to hydroxyethyl starch |
| Adverse reactions | <ul style="list-style-type: none"> • Anaphylactoid/Hypersensitivity (rare) – mild influenza-like symptoms, bradycardia, tachycardia, bronchospasm and non-cardiac-pulmonary oedema • Disturbance of blood coagulation can occur rarely depending on dosage (rare) • Mild and self-limiting pruritus (itching) is a known complication occurring in 10.2% of cases in a pivotal study (common) • Concentration of serum amylase can rise during administration (common) | <ul style="list-style-type: none"> • Anaphylactoid reaction/Hypersensitivity - wheezing, urticaria and hypotension • Coagulation disorder or hemorrhage have been reported • Elevated serum amylase levels may be observed temporarily following administration • Headache, diarrhea, nausea, weakness, temporary weight gain, insomnia, fatigue, fever, edema, paresthesia, acne, malaise, shakiness, dizziness, chest pain, chills, nasal congestion, anxiety, and decreased heart rate have been reported in clinical studies |

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|---|---|--|
| Attributes | Voluven® by Fresenius Kabi | Pentaspan™ by Bristol-Myers Squibb |
| Dosage form | Intravenous infusion only. | Intravenous infusion only. |
| Infusion rate & dosage | Infusion rate: Unspecified Dose: 33 mL/kg/day (limited experience with infusion up to 50 mL/kg/day) Can be administered repetitively over several days. | Infusion rate: 20 mL/kg/hour Dose: 28 mL/kg/day Use beyond 72 hours has not been studied. |
| Pharmacodynamics | Isovolemic exchange of blood maintains volume for at least 6 hours. | Infusion results in expansion in excess of volume infused lasting for approx. 18-24 hours and is expected to improve the hemodynamic status for 12-18 hours. |

This *Hydroxyethyl Starch Products Comparison Table* contains information specified in the Canadian product monographs, and is for reference purposes only. Please consult the product monograph or product insert for more detailed information.

The above table information is derived from data published in the Canadian Blood Services Customer Service Letter #2007-43, Reference 14.