HESPAN®
(6% hetastarch in 0.9% sodium chloride injection)

Proven cost-effectiveness,
Proven volume expansion lasting up to 24 hrs¹

A generation of trust
B. Confident
When used in combination fluid therapy with crystalloids, HESPAN can reduce post-operative complications.

POST-OP COMPLICATIONS *

![Graph showing incidence of post-operative complications](image)

- Nausea: 0.007
- Emesis: 0.02
- Use of Rescue Antiemetic: 0.006
- Severe Pain on Coughing: 0.002
- Orbital Edema & Double Vision: 0.03

*Adapted with permission from Moretti et al (2)

HESPAN is contraindicated in patients with the following conditions: known hypersensitivity to hydroxyethyl starch, bleeding disorders, congestive heart failure where fluid overload is a potential problem, renal disease with oliguria or anuria not related to hypovolemia.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product.

See brief summary of prescribing information on following page.

References:
**HESpan® (6% hetastarch in 0.9% sodium chloride injection)**

**DESCRIPTION**  HESpan® (6% hetastarch in 0.9% sodium chloride injection) is a sterile, nonpyrogenic solution for intravenous administration. Each 100 mL contains:

- Hetastarch — 6 g
- Sodium Chloride, USP — 0.9 g
- Water for Injection, USP — qs

Concentration of Electrolytes (mEq/L): Sodium 154, Chloride 154 pH: approximately 5.9 with negligible buffering capacity

Calcium: ordinarily 309 mM

Hetastarch is a synthetic colloid derived from a waxy starch composed almost entirely of amylopectin. Hydroxethyl ether groups are introduced into 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. Hetastarch is characterized by its mucous, substitution process and also the molecular size. The molecular substitution is approximately 0.75 which means hetastarch has an average of approximately 75 hydroxethyl groups for every 100 glucose molecules. The weight average molecular weight is approximately 600,000 with a range of 450,000 to 800,000 and with at least 80% of the polymers falling within the range of 20,000 to 6,000,000. Hydroxethyl groups are attached primarily at C-1 of the glucose unit and to a lesser extent at C-3 and C-6. The polymer resembles glycogen, and the polymerized D-glucose units are joined primarily by α-1,4 linkages with occasional α-1,6 branching linkages. The degree of branching is approximately 1.20 which means that there is an average of approximately one α-1,6 branching point for every 20 glucose monomer units.

The chemical name for hetastarch is hydroxethyl starch.

**The structural formula is as follows:**

\[
\text{R} \accentset{{}}{\text{OCH}_2CH}_2{\text{CH(OH)}_2H}_2\text{C}_{\text{R}} \text{Rho}\text{H} \text{OCH}_2\text{CH}_2\text{OH}
\]

Amylopectin derivate in which R and R' are H or CH2OH and R is H, CH2OH, or a branching point in the starch polymer connected through an α-1,6 link to additional D-glucopyranosyl units.

HESpan® is a clear, pale yellow to amber solution. Exposure to prolonged adverse storage conditions can result in clouding and the formation of a crystalline precipitate. Do not use the solution if these conditions are evident.

**The EXCEL® Container is Latex-free, PVC-free, and DEHP-free.**

**INDICATIONS AND USAGE**  HESpan® 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 HESpan® in leukapheresis has also been shown to be safe and efficacious in situations where a greater degree of plasma volume expansion is desired, in a daily setting, and when a colloid substitution is not dependent upon the simultaneous administration of red blood cells or plasma protein, albumin, calcium, and fibrinogen levels. None of these decreases are to a degree recognized to be clinically significant risks to healthy donors.

**WARNINGS**  Life threatening anaphylactic/anaphylactoid reactions have been rarely reported with HESpan®; death has occurred, but a causal relationship has not been established. Patients who develop severe anaphylactic/anaphylactoid reactions may need continued supportive care until symptoms have resolved.

Hypersensitivity reactions can occur even after HESpan® has been discontinued. Usage in Plasma Volume Expansion  HESpan® has not been adequately evaluated to establish its safety in situations other than treatment of hypovolemia in elective surgery.

Large volumes of HESpan® may transiently alter the coagulation mechanism due to hemodilution and a direct inhibitory action on Factor VIII. Administration of volumes of HESpan® that are greater than 25% of the blood volume in less than 24 hours may cause significant hemodilution reflected by lowered hematocrit and plasma protein values. Administration of packed red cells, platelets, or fresh frozen plasma should be considered if clinically indicated.

HESpan® is contraindicated in patients with known hypersensitivity to hydroxethyl starch. It is also contraindicated in clinical situations where volume overload is a potential problem, such as, congestive heart failure or renal disease with anuria or oliguria not related to hypovolemia.

Patients with pre-existing coagulation or bleeding disorders should not be given HESpan®.

**CONTRAINDICATIONS**  HESpan® is contraindicated in patients with known hypersensitivity to hydroxethyl starch. It is also contraindicated in clinical situations where volume overload is a potential problem, such as, congestive heart failure or renal disease with anuria or oliguria not related to hypovolemia.

**Patient Mothers: It is not known whether hetastarch is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when HESpan® is administered to a nursing woman.**

**DOSAGE AND ADMINISTRATION**  Usage in Leukapheresis  Slight declines in platelet counts and hemoglobin levels have been observed in donors undergoing repeated leukapheresis procedures using HESpan® due to the volume expanding effects of hetastarch and to the collection of platelets and erythrocytes. Hemoglobin levels usually return to normal within 24 hours. Hemodilution by HESpan® may also result in 24 hour declines of total protein, albumin, calcium, and fibrinogen levels. None of these decreases are to a degree recognized to be clinically significant risks to healthy donors.

**PRECAUTIONS**  General  If administration is by pressure infusion, all air should be withdrawn or expelled from the bag through the medication port prior to infusion.

Caution should be used when administering HESpan® in patients with chronic anemia. Administration of HESpan® in patients who have been sensitized to heparin or heparin-related antigens will increase the risk of developing heparin neutralizing antibodies.
B. Braun practices the open exchange of information among employees, partners and customers from around the world. This collective expertise enables B. Braun to translate customer needs into the development of innovative safety products, programs, and services all based on superior technologies, quality, cost efficiencies, and environmental responsibility. By sharing expertise, we contribute to the safety and quality of healthcare professionals and their patients.

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