▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

NAME OF THE MEDICINAL PRODUCT

Venofundin 60 mg/ml solution for infusion

COMPOSITION

1000 ml of solution contain:

Hydroxyethyl starch (HES)	60.0 g
(Molar substitution:	0.42)
(Average molecular weight:	130,000 Da)

Sodium chloride 9.0 g

Electrolyte concentrations:

Sodium	154 mmol/l
Chloride	154 mmol/l

Excipient: Water for Injections.

THERAPEUTIC INDICATIONS

Treatment of hypovolaemia due to acute blood loss when crystalloids alone are not considered sufficient.

CONTRAINDICATIONS

Hypersensitivity to the active substances or to any of the other excipients listed.

Sepsis; burns; renal impairment or renal replacement therapy; intracranial or cerebral haemorrhage; critically ill patients (typically admitted to the intensive care unit); hyperhydration; pulmonary oedema; dehydration; severe hypernatraemia or severe hyperchloraemia; severely impaired hepatic function; congestive heart failure; severe coagulopathy; organ transplant patients.

Special warnings and precautions for use
Because of the risk of allergic (anaphylactic / anaphylactoid) reactions, the patient should be monitored closely and the infusion instituted at a low rate.
The indication for volume replacement with Hydroxyethyl starch has to be considered carefully, and haemodynamic monitoring is required for volume and dose control.
Sufficient fluid intake must be ensured.
Volume overload due to overdose or too rapid infusion must always be avoided. The dosage must be adjusted carefully, particularly in patients with pulmonary or cardiocirculatory problems. Serum electrolytes, fluid balance and renal function should be monitored closely. Electrolytes and fluids should be substituted according to individual requirements.
Hydroxyethyl starch products are contraindicated in patients with renal impairment or renal replacement therapy. The use of Hydroxyethyl starch must be discontinued at the first sign of renal injury. An increased need for renal replacement therapy has been reported up to 90 days after Hydroxyethyl starch administration. Monitoring of renal function in patients is recommended for at least 90 days.
Particular caution should be exercised when treating patients with impaired hepatic function or in patients with blood coagulation disorders.
Severe haemodilution resulting from high doses of Hydroxyethyl starch solutions must also be avoided in the treatment of hypovolaemic patients.
In the case of repeated administration, blood coagulation parameters should be monitored carefully. Discontinue the use of Hydroxyethyl starch at the first sign of coagulopathy.
In patients undergoing open heart surgery in association with cardiopulmonary bypass the use of Hydroxyethyl starch products is not recommended due to the risk of excess bleeding.

Elderly patients
Elderly patients, who are more likely to suffer from cardiac insufficiency and renal impairment, should be closely monitored during treatment, and the dosage should be carefully adjusted, in order to avoid cardiocirculatory and renal complications resulting from hypervolaemia.

Surgery and trauma:
There is a lack of robust long term safety data in patients undergoing surgical procedures and in patients with trauma. The expected benefit of treatment should be carefully weighed against uncertainty with regard to this long term safety. Other available treatment options should be considered.

Paediatric population:
Data are limited in children therefore it is recommended not to use Hydroxyethyl starch products in this population.

Influence on laboratory tests
Transiently raised alpha-amylase levels can occur after administration of solutions with Hydroxyethyl starch. This should not be interpreted as evidence of pancreatic disorder.

UNDESIRABLE EFFECTS

Undesirable effects are listed according to their frequencies as follows:

Very common: (≥ 1/10)
Common: (≥ 1/100 to < 1/10)
Uncommon: (≥ 1/1 000 to < 1/100)
Rare: (≥ 1/10 000 to < 1/1000)
Not known: (cannot be estimated from the available data)

General
The most common side effects observed (very common, ≥1/10) are directly related to the therapeutic effects of starch solutions and the volume given, *i.e.*, dilution of the blood as a result of the filling of the intravascular space without administering blood components at the same time. Coagulation factor dilution can also occur. Serious anaphylactic/anaphylactoid reactions have been reported and may require immediate action (please refer also to the section “Anaphylactic/Anaphylactoid reactions” below)

System organ class

Blood and lymphatic system disorders
Very common: Decreased haematocrit, reduced concentration of plasma proteins.
Common: Dilution of coagulation factors, prolongation of bleeding time and aPTT, reduced level of FVIII/vWF complex (1)

Hepatobiliary disorders
Not known: Hepatic injury

Immune system disorders
Rare: Anaphylactoid reactions of various degrees (see "Anaphylactoid reactions" below)

Renal and urinary disorders
Not known: Renal injury

General disorders and administration site conditions
Uncommon: Itching which responds poorly to any therapy (2)

Investigations
Very common: Increased serum α-amylase levels (3)

(1) Effects occur after administration of relatively large volumes of Hydroxyethyl starch and can affect blood coagulation.

(2) This itching can occur several weeks after the end of the starch infusions and can persist for months. The probability of this undesirable effect has not been sufficiently studied for Venofundin 60 mg/ml.

(3) This effect is a result of the formation of an amylase complex of Hydroxyethyl starch with delayed renal and extrarenal elimination. This should not be misinterpreted as evidence of a pancreatic disorder.

Anaphylactic / Anaphylactoid reactions

After administration of Hydroxyethyl starch, anaphylactic / anaphylactoid reactions of various degrees can occur which are not dose-dependent. Therefore, all patients receiving starch infusion should be monitored closely for anaphylactic / anaphylactoid reactions. In the event of an anaphylactic / anaphylactoid reaction, the infusion should be discontinued immediately and the usual acute treatment given.

It is not possible to predict by tests which patients may be expected to suffer an anaphylactic / anaphylactoid reaction nor is it possible to predict the course and severity of such a reaction.

Prophylaxis with corticosteroids has not been shown to have a preventive effect.

WARNINGS

Keep out of sight and reach of children.

DO NOT USE IN SEPSIS, RENAL IMPAIRMENT, OR CRITICALLY ILL PATIENTS. SEE ALL CONTRAINDICATIONS IN THE SMPC.

For single use only. Discard unused content after use. Use only if the solution is clear, colourless and the container is undamaged. Use immediately after first opening. Expel all air before starting pressure infusion.

NOTE

Prescription only

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

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