▼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

Tetraspan 60 mg/ml solution for infusion

COMPOSITION

1 000 ml of Tetraspan 60 mg/ml solution for infusion contain:

Hydroxyethyl starch (HES) (Molar substitution: (Average molecular weight:	60.0 g 0.42) 130,000 Da)
Sodium chloride	6.25 g
Potassium chloride	0.30 g
Calcium chloride dihydrate	0.37 g
Magnesium chloride hexahydrate	0.20 g
Sodium acetate trihydrate	3.27 g
L-Malic acid	0.67 g
Electrolyte concentrations:	
Sodium	140 mmol/l
Potassium	4.0 mmol/l
Calcium	2.5 mmol/l
Magnesium	1.0 mmol/l
Chloride	118 mmol/l
Acetate	24 mmol/l
L-Malate	5.0 mmol/l

Excipients: Sodium hydroxide (for pH adjustment), 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.
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; hyperkalaemia; severe hypernatraemia or severe hyperchloraemia; severely impaired hepatic function; congestive heart failure; severe coagulopathy; organ transplant patients.

UNDESIRABLE EFFECTS

General
The most common side effects observed are directly related to the therapeutic effect 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).

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)

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: Anaphylactic/Anaphylactoid reactions of various degrees (see " Anaphylactic/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 Tetraspan 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 initiated.

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 the 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 contents. Use immediately after first opening.
Use only if solution is clear and the container and closure are undamaged.
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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