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- Superior haemodynamic stability in goal-directed therapy compared to crystalloids[3,4]
- No clinical evidence for harmful effects on renal function in surgery compared to crystalloids[5]

Disclaimer: The above cited studies refer to surgical settings. Please note that special warnings and precautions for using Voluven®/Volulyte® in surgery exist in Europe which require special care and stipulate the use with caution. Therefore, please refer to the prescribing information below as well as to the locally applicable SmPC.

References: 1. Jacob M et al. Anaesthesist 2003; 52: 896-904; **2.** Jacob M et al. Crit Care 2012; 16: R86; **3.** Zhang J et al. Clinics 2012; 67: 1149-1155; **4.** Lindroos AC et al. Acta Anaesthesiol Scand 2013; 57: 729-736; **5.** Kancir et al. Anesthesiology 2014; 121(5): 948-958

Name of the Medicinal product: Voluven® Fresenius 6% Solution for Infusion / Volulyte® 6% Solution for Infusion.

▼ This medicinal product is subject to additional monitoring.

Please contact pharmacovigilance@fresenius-kabi.com, if you would like to report adverse reactions.

Composition: 1000 ml contain: Poly(0-2-hydroxyethyl)starch 60.00 g (molar substitution 0.38 - 0.45; mean molecular weight: 130,000 Da), sodium chloride 9.00/6.02 g, sodium acetate trihydrate ~/4.63 g, potassium chloride ~/0.30 g, magnesium chloride hexahydrate ~/0.30 g, Na^+ 154/137 mmol, Cl^- 154/110 mmol, K^+ ~/4 mmol, Mg^{2+} ~/1.5 mmol, CH_3COO^- ~/34 mmol; theoretical osmolarity 308/286.5 mosmol/l, pH 4.0-5.5/5.7-6.5, titratable acidity < 1.0/< 2.5 mmol NaOH/l. **Therapeutic indications:** Treatment of hypovolaemia due to acute blood loss when crystalloids alone are not considered sufficient. **Posology and method of administration:** For intravenous use as infusion. Use of HES should be restricted to the initial phase of volume resuscitation with a maximum time interval of 24 h. The first 10-20 ml should be infused slowly and under careful monitoring of the patient so that any anaphylactic/anaphylactoid reaction can be detected as early as possible. The daily dose and rate of infusion depend on the patient's blood loss, on the maintenance or restoration of haemodynamics and on the haemodilution (dilution effect). The maximum daily dose is 30 ml/kg for Voluven® Fresenius 6 % / Volulyte®. The lowest possible effective dose should be applied. Treatment should be guided by continuous haemodynamic monitoring so that the infusion is stopped as soon as appropriate haemodynamic goals have been achieved. The maximum recommended daily dose must not be exceeded. Data are limited in children, therefore it is recommended not to use HES products in this population. **Contraindications:** Hypersensitivity to the active substances or to any of the other excipients (sodium hydroxide, hydrochloric acid, water for injections), 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 hyperkalaemia, severe hypernatraemia or severe hyperchloraemia, severely impaired hepatic function, congestive heart failure, severe coagulopathy, organ transplant patients. **Special warnings and special precautions for use:** Volume overload due to overdose or too rapid infusion must always be avoided. The dosage must be adjusted carefully, particularly in patients with pulmonary and cardiocirculatory problems. Serum electrolytes, fluid balance and renal function should be monitored closely. The use of HES 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 HES 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 HES 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 HES at the first sign of coagulopathy. In patients undergoing open heart surgery in association with cardiopulmonary bypass the use of HES products is not recommended due to the risk of excess bleeding. 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. Only Volulyte®: Particular care must be taken in patients with electrolyte abnormalities, like hyperkaliaemia, hypernatraemia, hypermagnesaemia and hyperchloraemia. In metabolic alkalosis and clinical situations where alkalisation should be avoided, saline based solutions like Voluven® Fresenius 6 % should be preferred over alkalising solutions like Volulyte®. **Pregnancy and lactation:** For Voluven® Fresenius 6 % / Volulyte® no clinical data on exposed pregnancies are available. There are limited clinical study data available from the use of a single dose of HES 130 / 0.4 in 0.9 % sodium chloride solution in pregnant women undergoing caesarean section with spinal anaesthesia. No negative influence of HES 130 / 0.4 in 0.9 % sodium chloride solution on patient safety could be detected; a negative influence on the neonate could also not be detected. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo / foetal development, parturition or postnatal development. No evidence of teratogenicity was seen. Voluven® Fresenius 6 % / Volulyte® should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. It is unknown whether hydroxyethyl starch is excreted in human breast milk. The excretion of hydroxyethyl starch in milk has not been studied in animals. A decision on whether to continue / discontinue breast-feeding or to continue / discontinue therapy with Voluven® Fresenius 6 % / Volulyte® should be made taking into account the benefit of breast-feeding to the child and the benefit of Voluven® Fresenius 6 % / Volulyte® therapy to the woman. Only Voluven® Fresenius 6 %: There are currently no clinical data available on the use of Voluven® Fresenius 6 % in lactating women. **Undesirable effects:** *Rare:* With the administration of hydroxyethyl starch disturbances of blood coagulation can occur depending on the dosage. Medicinal products containing hydroxyethyl starch may lead to anaphylactic / anaphylactoid reactions (hypersensitivity, mild influenza-like symptoms, bradycardia, tachycardia, bronchospasm, non-cardiac pulmonary oedema). In the event of an intolerance reaction occurring the infusion should be discontinued immediately and the appropriate emergency medical treatment initiated. *Common:* Prolonged administration of high dosages of hydroxyethyl starch may cause pruritus (itching). The concentration of serum amylase level can rise during administration of hydroxyethyl starch and can interfere with the diagnosis of pancreatitis. At high dosages the dilution effects may result in a corresponding dilution of blood components such as coagulation factors and other plasma proteins and in a decrease of hematocrit. *Frequency not known:* Hepatic and renal injury. **Overdose:** As with all volume substitutes, overdose can lead to overloading of the circulatory system (e.g. pulmonary oedema). In this case the infusion should be stopped immediately and if necessary, a diuretic should be administered. **Issue of information:** January 2014.

Registered Product Information may differ in your country. For further information and before prescribing refer to the nationally approved SmPC.

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