Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Gelofusine 40 mg/ml

solution for infusion

Composition

Active substances:

1000 ml of solution contain(s)

Gelatine polysuccinate (= modified fluid gelatine) (Molecular weight, weight average: 30 000 Dalton Molecular weight, number average: 23 200 Dalton)	40.0 g
Sodium chloride	7.01 g

Electrolyte concentrations

Sodium	154 mmol/l
Chloride	120 mmol/l

Excipients:
Sodium hydroxide, water for injections

Pharmaceutical form

Solution for infusion

Physico-chemical characteristics

pH		7.4 ± 0.3	
Relative viscosity (37 °C)		1.9	
Isoelectric point	pH	4.5 ± 0.3	
Colloid osmotic pressure		453	mm H_2O
		33.3	mm Hg
Theoretical osmolarity		274	mosm/l
Gelation point		≤ 3	°C

Pharmaco-therapeutic group

Blood substitutes and plasma protein fractions, ATC code: B05A A06, gelatin agents

Indications

- Prophylaxis and treatment of relative or absolute hypovolaemia and of shock;
- Prophylaxis of hypotension (e.g. during induction of epidural or spinal anaesthesia);
- Procedures involving extracorporal circulation (e.g. heart-lung machine);
- Acute normovolaemic haemodilution.

Contraindications

Gelofusine must not be administered in the case of:

- hypersensitivity to any of the constituents of the solution,
- hypervolaemia,
- hyperhydration,
- severe cardiac insufficiency,
- severe blood coagulation disorders.

Special warnings and precautions for use

Gelofusine should be administered with caution to patients with a history of allergic diseases, e.g. asthma.

Gelatin preparations for volume replacement may rarely cause anaphylactoid reactions of varying degrees of severity. In order to detect the occurrence of an anaphylactoid reaction as early as possible, the first 20 – 30 ml should be infused slowly and under careful observation of the patient. Details of symptoms of anaphylactoid reactions and emergency measures, see section **Undesirable effects**.

Gelofusine should only be administered with caution to

- elderly patients
- patients at risk due to circulatory overload e.g. patients with congestive heart failure, right or left ventricular insufficiency, hypertension, pulmonary oedema or renal insufficiency with oligo- or anuria.

In such cases Gelofusine should only be given under careful monitoring of the patient's hamodynamic situation.

There is no sufficient experience with the use of Gelofusine in children. Therefore, Gelofusine should be used in children only after careful benefit-risk assessment, and with careful monitoring.

Checks of serum electrolyte concentrations and water balance are necessary, in particular in patients with hypernatraemia, hypokalaemia, dehydration, or impairment of renal function.

Special attention should be paid to the appearance of symptoms of hypocalcaemia (e.g. signs of tetany, paraesthesia); then specific corrective measures should be taken.

In states of dehydration the fluid deficit must be corrected first. Electrolytes should be substituted as required.

During compensation of severe blood losses by infusions of large amounts of Gelofusine, the haematocrit must be monitored under any circumstances. The haematocrit should not decrease below the critical values stated in section **"Dosage".**

Likewise in those situations the dilution effect on coagulation factors should be observed, especially in patients with existing disorders of haemostasis.

Because the product does not substitute lost plasma protein, it is advisable to check the plasma protein concentrations, see also section **Dosage,** "Maximum dose".

Interference with laboratory tests

Gelofusine may have an influence on the following clinical-chemical tests, leading to falsely high values:

- erythrocyte sedimentation rate,
- specific gravity of urine,
- unspecific protein assays, e.g. the biuret method.

Interactions

Pharmacological interactions are not known

Pregnancy and lactation

Controlled studies have been carried out neither in animals nor in pregnant women.

Because of possible anaphylactic or anaphylactoid reactions, the preparation should only be administered during pregnancy, if the indication is imperative, and solely if the potential benefit is greater than the foetal risk.

It is not known whether Gelofusine passes into breast milk. Sufficient experience with application during the breast-feeding period is not available.

Dosage

Recommended dosage schedule

Adults

Dosage and infusion rate are adjusted according to the amount of blood loss and to individual needs for restoration and maintenance of a stable haemodynamic situation, respectively. The effect of volume substitution is controlled by monitoring blood pressure, central venous pressure, heart rate, diuresis rate, haemoglobin concentration, haematocrit etc..

Paediatric patients

As documented experience regarding the use of Gelofusine in children is insufficient, the dosage must be adjusted very carefully according to the individual requirements for restoration and maintenance of normal haemodynamic status and circulating fluid volume. See also section 4.4.

Maximum dose:

From the toxicological point of view there are no limitations of the dose. The maximum daily dose is determined by the degree of haemodilution. Care must be taken to avoid a decrease of the haematocrit below critical values.

Values regarded to be critical for the patient vary interindividually, depending, *inter alia,* on capillary oxygen extraction, the patient's age, circulatory reserve and prevailing clinical condition. In patients with normal oxygen requirement and unimpaired compensatory mechanisms, haemodilution down to a haemoglobin level of 8 g/100 ml or a haematocrit of 25 % may be acceptable; in patients in intensive care the haemoglobin must not fall below 10 g/100 ml or the haematocrit not below 30 %. If necessary, blood or packed red cells must be transfused additionally. Attention must also be paid to the dilution of plasma proteins (e.g. albumin and coagulation factors), which must be adequately substituted if necessary.

Infusion rate:

The infusion rate depends on the actual haemodynamic situation. Usually, 500 ml are infused over 30 min. However, the first 20 – 30 ml of solution should be infused slowly in order to detect the occurrence of an anaphylactoid reaction as early as possible. See also sections **Special warnings and precautions for use** and **Undesirable effects.**

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In vital emergencies, Gelofusine may be infused rapidly by pressure infusion, 500 ml within 5 – 10 min.
Too rapid infusion may lead to circulatory overload.

Method of administration

Intravenous use.

The solution should be warmed to body temperature prior to infusion.

When giving Gelofusine by pressure infusion using a pressure cuff, all air must be removed from containers with air space inside and from the infusion set before the solution is administered.

Overdose

Symptoms

Overdose or too rapid infusion of Gelofusine would lead to unintended hypervolaemia and circulatory overload, associated with consecutive impairment of heart and lung function. Symptoms of circulatory overload are e.g. headache, dyspnoea, and jugular vein congestion.

Emergency treatment , antidotes
As soon as symptoms of circulatory overload appear, the infusion must be stopped immediately. Therapy is symptomatic. Administration of a diuretic may be necessary.

Undesirable effects
Immune system disorders
Rare (≥ 1/10 000 to < 1/1 000)
Anaphylactoid reactions (all grades). (Details see section "Anaphylactoid reactions" below)
Very rare (< 1/10 000)
Severe anaphylactoid reactions (grade III or IV)(Details see section "Anaphylactoid reactions" below)

Gastrointestinal disorders
Uncommon (≥ 1/1 000 to < 1/100): Transient mild nausea or abdominal pain

General disorders
Uncommon (≥ 1/1 000 to < 1/100): Transient mild rise of body temperature

Anaphylactoid reactions
After the administration of Gelofusine infusions, just as of any colloidal volume substitutes, anaphylactoid reactions of varying degrees of severity may occur. These reactions manifest as fever, cutaneous eruptions (urticaria) or sudden flushing of face and neck and a drop of blood pressure. In rare cases they may proceed to shock, cardiac and respiratory arrest.

Severe anaphylactoid reactions (grade III or IV) are very rare (incidence < 1 : 10 000). Patients receiving Gelofusine must be continuously observed for the occurrence of anaphylactoid reactions.

General guidelines for the prophylaxis of adverse reactions:
- Adequate information of physicians and nursing staff about the type and severity of possible adverse reactions that may be encountered after the administration of a colloidal volume substitute.
- Close observation of the patient during infusion, especially while the first 20 – 30 ml of the solution are being infused.
- Availability of all apparatus and medication required for resuscitation.
- Stop of infusion immediately, as soon as there are any indications of adverse reactions.
  Emergency treatment of anaphylactoid reactions follows established schedules, depending on the severity of the reaction[1].

It cannot be predicted by any test procedure which patients are likely to experience anaphylactic or anaphylactoid reactions, nor is it possible to foresee the course and severity of any such reaction.

Anaphylactoid reactions caused by gelatine solutions may ether be histamine-mediated or histamine independent. Histamine release can be prevented by the use of a combination of H_1- and H_2 receptor blockers.

Prophylactic administration of corticosteroids has not proven effective.

Adverse reactions may occur in conscious and anaesthetized patients. In the acute phase of volume deficiency shocks so far no anaphylactic or anaphylactoid reaction has ever been reported.

Expiry date
The product must not be used beyond the expiry date stated on the labelling.

Instructions for storage / use / handling
Do not store above 25 °C. Do not freeze.

The product is supplied in single-dose containers. Unused contents of an opened container must be discarded.

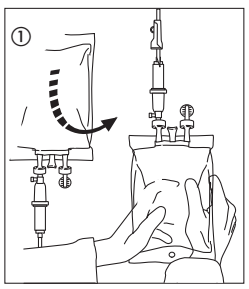
Only to be used if solution is clear and free of precipitate and the container undamaged.

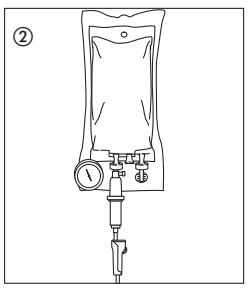
Use immediately after connecting container to the giving set.

After admixture of an additive start administration immediately.

Date of last revision
04.2010

Handling Instructions Ecobag®

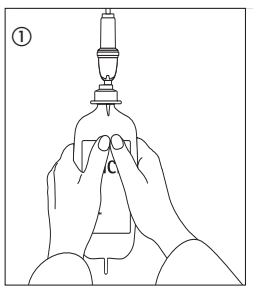


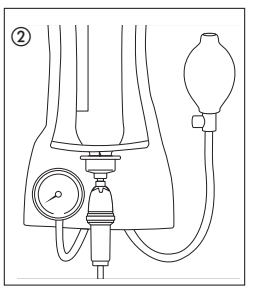


①
Pressure infusion
– Insert infusion set.
– Hold container upright.
– Leave clamp open, expel air from container and fill half of drip chamber.
– Turn container and expel air from infusion device.
– Close clamp.

②
– Place container in pressure cuff.
– Build up pressure.
– Open clamp and start infusion.

Handling Instructions Ecoflac® plus





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[1] e.g. Adams HA et al.: Empfehlungen zur Diagnostik und Therapie der Schockformen der IAG Schock der DIVI, Teil 4: Anaphylaktischer Schock
Intensivmed.42 (2005): 299 – 304