

Data Sheet

GELAFUSAL®

Presentation

Gelafusal is a 4% solution of succinylated gelatin for intravenous infusion, presented in 500 ml flexible packs.

Gelafusal contains in 1000 ml:

Gelatin polysuccinate	40.0 g
Sodium acetate trihydrate	3.675 g
Sodium chloride	4.590 g
Potassium chloride	0.403 g
Calcium chloride dihydrate	0.133 g
Magnesium chloride hexahydrate	0.203 g
Sodium hydroxide	0.980 g
Water for injections	q.s.

Electrolyte composition: mmol/L

Sodium	130
Potassium	5.4
Calcium	0.9
Magnesium	1.0
Chloride	85
Acetate	27

Characteristics:

Clear, slightly yellow, sterile, endotoxin-free solution for infusion.

Molecular weight average M_w	30,000
Molecular weight number M_n	22,600
pH	7.1 – 7.7
Theoretical osmolarity	279 mOsm/L
Titrateable acidity	0.5 mmol/L up to pH 7.4

Uses

Actions

Gelatin 4% is a colloid plasma volume substitute. The colloid osmotic pressure of the solution is 34 mm Hg and corresponds with a normal patient value (27 mm Hg). The increase in the plasma volume initially corresponds with the infused volume. Gelatin 4% is rapidly distributed in the blood after intravenous infusion, achieving a volume effect that lasts 3 – 4 hours.

Dehydration of the extravascular space does not occur. Haemostasis is not disturbed. Apart from the dilution effect, blood coagulation is not otherwise affected. There is no effect on blood group analysis or the rhesus factor.

Gelatin 4% stimulates diuresis by increasing the fluid and electrolyte supply. This osmotic diuresis can prevent oliguria or anuria and can significantly reduce the effect of shock on the kidney.

The low calcium content allows use in patients receiving digoxin. Potassium overload is not a concern because the potassium content of gelatin 4% corresponds with physiological values.

Pharmacokinetics

There is no storage in tissues or organs. Most infused gelatin is excreted through the kidney and the low molecular weight fraction is excreted in the first hour. Approximately 8% of the infused gelatin is eliminated by the intestines. Approximately 60% of the infused gelatin is excreted in the urine within the first 24 hours.

Indications

Prevention and treatment of volume deficiency and shock.

Preoperative haemodilution.

Dosage and administration

For intravenous use, the dosage and infusion rate are based on individual requirements and adapted to the patient's particular needs by monitoring the usual circulatory parameters. The following dosage recommendations are approximate and apply to adults:

1. Small volume losses and stabilisation of the circulation before and during surgery: 500 – 1000 ml.
2. Larger volume losses, onset of shock: 1000 – 1500 ml.
3. Fully developed shock: up to 2500 ml and more, depending on the volume loss.

Rapid infusion (pressure infusion) is possible.

Since the symptoms of shock are not apparent until a volume loss of at least 1000 ml has occurred, a rapid infusion with positive pressure within 10 – 15 minutes is recommended in such cases.

4. In emergencies with circulatory collapse: start with pressure infusion up to 500 ml; once the circulatory situation has improved, normal infusion depending on volume loss.

Owing to the risk of anaphylactic/anaphylactoid side effects, the patient should be kept under close observation while the first 20 – 30 ml are being infused.

The therapeutic limit (maximum daily dose) is determined by dilution effects. The haematocrit regarded as critical for a particular patient should be decided on an individual basis and should be guided by the clinical situation. It is essential to watch for any dilution of plasma proteins (including clotting factors) and to ensure that they are replaced as required. There is a risk of overloading the circulation if the infusion is given too quickly.

The duration of treatment is determined by the clinical situation.

Contraindications

Absolute contraindications

Hyperhydration

Hypervolaemia

Serious cardiac insufficiency

Renal impairment

Hypersensitivity to any of the ingredients

Severe blood clotting disorders.

Relative contraindications

Coagulation disorders

Hypernatraemia

Hyperkalaemia

States of dehydration

Diseases requiring restriction of sodium intake.

Pulmonary oedema

Intracranial haemorrhages

In the case of afibrinogenaemia, only in life-threatening emergencies.

Warnings and precautions

Anaphylactoid/anaphylactic reactions

In common with all colloidal plasma volume substitutes, gelatin 4% can cause anaphylactoid/anaphylactic reactions of varying severity, ranging from benign skin symptoms (urticaria) through flushing of the face and neck, to the much less frequent but more severe reactions involving acute decrease in blood pressure, shock, bronchospasm, cardiac or respiratory arrest. Such reactions can occur in conscious and anaesthetised patients. Patients receiving gelatin 4% have to be carefully observed in cases of potential anaphylactoid/anaphylactic reactions. The use of gelatin 4% should be avoided in patients with a known history of drug allergy because of the greater risk of anaphylactoid/anaphylactic reactions with colloidal plasma substitutes.

Treatment guidelines

Since incompatibility reactions occur very soon after the start of the infusion, it is important to observe patients during administration of the first 20 to 30 ml (test infusion).

If there are signs of incompatibility, the infusion must be stopped immediately. The following measures are recommended in the event of serious developments: Therapy for an anaphylactoid reaction is determined by the seriousness of the reaction and must take the form of emergency therapy if classified as life-threatening category III and IV.

Stage	Symptoms	General measures	Special medication
I	Skin reaction: Flush, urticaria. Subject agitated or complains of headache.	Stop infusion.	If necessary, H ₁ /H ₂ antagonists. Corticosteroids if known to be disposed to allergy
II	Cardiovascular and/or pulmonary and possibly gastric reactions.		Adrenaline inhalation or 1 mg/10 ml slow IV. (0.1 mg/min) Corticosteroids and H ₁ /H ₂ antagonists if necessary.

III	Serious general reaction (shock, bronchial spasm, serious dyspnoea and/or consciousness disturbances)	Supply oxygen. Fluid therapy (Infuse colloid or crystalloid solutions)	Catecholamine/ Adrenaline up to 1mg. With progression: Noradrenaline or dopamine. H ₁ /H ₂ antagonists if necessary. With bronchial spasms: Theophylline IV and corticosteroids if necessary.
IV	Vital organ failure (breathing cardiovascular collapse.)	Cardiopulmonary resuscitation.	Catecholamine Adrenaline. Repeat as necessary in combination with noradrenaline, dopamine and dobutamine.

Pregnancy and lactation

Experience with gelatin 4% during pregnancy and lactation is insufficient to recommend treatment. Gelatin 4% should therefore only be given after careful weighing up of advantages and risks.

Effects on ability to drive and use machines

Nil

Other

If patients with extracellular dehydration or acute renal failure are given gelatin 4%, suitable electrolytes must also be given to maintain or restore a normal fluid and electrolyte balance. In the case of afibrinogenaemia, colloid replacement solutions may only be given in life-threatening emergencies until replacement blood is available. Tests for fluid and electrolyte balance are necessary. Depending on the infused volume, monitoring for dilution of the plasma proteins (coagulation factors, albumin) should be carried out. If dilution is detected, appropriate substitution is required.

Adverse effects

As with all colloidal plasma volume substitutes allergic reactions of varying severity can occur with gelatin solutions. The severity of these reactions depends on the individual's reactivity. They usually take the form of skin reactions (e.g. redness, itchy rash). A temperature increase, shivers, blood pressure increase and blood pressure decrease may also be observed. In exceptional cases, severe side effects with circulatory involvement (shock symptoms) may occur. Since these intolerance reactions appear very soon after the start of the infusion, the patient should be carefully monitored while the first 20 to 30 ml are being run in (trial infusion).

In addition, there have been reports of bradycardia, tachycardia, flush, cardiac arrest, bronchospasm, dyspnoea and nausea with gelatin infusions. The infusion must be stopped immediately if there are any signs of intolerance.

Interactions

Gelatin infusion can cause false results for the following clinical chemistry and physical investigations: blood sugar, erythrocyte sedimentation rate (ESR), specific gravity of urine,

serum protein (by Biuret method), fatty acids, cholesterol, fructose and sorbitol dehydrogenase.

Overdosage

Hypervolaemia may occur if the dose is too high or if the infusion is given too quickly. At the first sign of circulatory overload, increased central venous pressure or pulmonary oedema, the infusion must be stopped immediately. Diuresis and cardiac function should be supported, depending on the clinical picture.

Pharmaceutical precautions

Instructions for use

Do not use unless the solution is clear and free from particles. Discard any left-over solution. Use bag un-vented.

Incompatibilities

Incompatible with solutions containing phosphate or carbonate.

Shelf life

The product has a shelf life of 36 months from the date of manufacture.

Store at or below 25 °C. Use immediately after opening.

Medicine classification

General sale medicine

Package quantities

10 x 500 ml flexible packs.

Name and address

Distributed in New Zealand by:

Biomed Limited
52 Carrington Road
Point Chevalier
Auckland,
NEW ZEALAND
Telephone 0800 833 133

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