B. Braun Melsungen AG · 34209 Melsungen, Germany

Gelaspan 4% solution for infusion

Composition
1000 ml solution contains:

Active substances:

Succinylated gelatine (= modified fluid gelatine) (Molecular weight, weight average: 26 500 Dalton)	40.0 g
Sodium chloride	5.55 g
Sodium acetate trihydrate	3.27 g
Potassium chloride	0.30 g
Calcium chloride dihydrate	0.15 g
Magnesium chloride hexahydrate	0.20 g

Electrolyte concentrations

Sodium	151 mmol/l
Chloride	103 mmol/l
Potassium	4 mmol/l
Calcium	1 mmol/l
Magnesium	1 mmol/l
Acetate	24 mmol/l

Excipients:
Sodium hydroxide (for pH adjustment),
Hydrochloric acid (for pH-adjustment),
Water for injections

Pharmaceutical form
Solution for infusion
Clear, colourless or slightly yellowish solution
Theoretical osmolarity: 284 mosmol/l
pH: 7.4 ± 0.3

Pharmacotherapeutic group
Blood substitutes and plasma protein fractions
ATC code: B05A A06, gelatine agents.

Indications
Gelaspan is a colloidal plasma volume substitute in an isotonic, fully balanced electrolyte solution for:
- Treatment of relative or absolute hypovolaemia and shock
- Prophylaxis and treatment of hypotension
  - caused by relative hypovolaemia during induction of epidural or spinal anaesthesia
  - due to imminent significant blood loss in a surgical setting
- Procedures involving extracorporeal circulation as a component of priming fluid in combination with crystalloid solutions (e.g. priming of heart-lung machines)

Contraindications
- hypersensitivity to active substance or to any of the excipients
- hypervolaemia
- hyperhydration
- acute congestive heart failure
- severe hypernatraemia
- severe hyperchloraemia

Special warnings and precautions for use
Gelaspan should be administered with caution to patients with a history of allergic diseases, e.g. asthma.

Gelatine preparations for volume replacement may rarely cause allergic (anaphylactic/anaphylactoid) reactions of varying degrees of severity. In order to detect the occurrence of an allergic reaction as early as possible, the first 20 ml should be infused slowly and the patient should be under careful observation especially at the beginning of the infusion.

Caution must be exercised in patients suffering from alpha-gal allergy (mammal meat allergy). There is a higher probability that these patients are sensitive to gelatine solutions.

In case of an allergic reaction, the infusion must be stopped immediately and appropriate treatment given.

Gelaspan should be administered only with caution to patients
- at risk due to circulatory overload e.g. patients with right or left ventricular insufficiency, hypertension, pulmonary oedema or renal insufficiency with oligo- or anuria.
- with severely impaired renal function
- with oedema with water/salt retention
- with major blood coagulation disorders
- of advanced age as these are more prone to develop disorders such as cardiac or renal insufficiency.
- severe hypercalcaemia
- in case of pre-existing hyperkalaemia, caution should be exercised and the solution should only be administered if it is clear that the benefits outweigh the risks.

As with all colloids, Gelaspan should only be used if hypovolaemia can not be sufficiently treated with crystalloids alone. In severe hypovolaemia colloids are usually applied in combination with crystalloids.

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.

Checks of serum electrolyte concentrations, acid-base balance, and water balance are necessary, in particular in patients with hypernatraemia, hyperchloraemia or impairment of renal function.

Electrolytes and fluids should be substituted according to individual requirements if necessary.

The haemodynamic, haematological and coagulation system should be monitored.

During compensation of severe blood losses by infusions of large amounts of Gelaspan, haematocrit and electrolytes must be monitored under all circumstances.

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'.

Gelaspan must not be infused through the same infusion line together with blood or blood products (packed cells, plasma and plasma fractions).

Paediatric population
There is insufficient experience with the use of Gelaspan in children. Therefore Gelaspan should only be administered to these patients if the expected benefits clearly outweigh potential risks. (See also section 'dosage')

Influence on laboratory tests
Laboratory blood tests (blood group or irregular antigens) are possible after Gelaspan infusions. Nevertheless it is recommended to draw blood samples before the infusion of Gelaspan in order to avoid hampered interpretation of results.

Gelaspan 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 with other medicinal products and other forms of interaction
Caution should be exercised in patients concurrently taking or receiving medicinal products that can cause sodium retention (e.g. corticosteroids, non-steroidal anti-inflammatory agents) as concomitant administration may lead to oedema.

Potassium, sparing diuretics, ACE inhibitors, non-steroidal anti-inflammatory agents, cyclosporine, tacrolimus or suxamethonium can increase the serum potassium level. The concomitant administration of potassium-containing solutions and these drugs may lead to severe hyperkalaemia, which in turn may lead to cardiac arrhythmia.

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Administration of potassium can reduce the therapeutic effect of cardiac glycosides.

ACTH, corticosteroids and loop diuretics can increase the renal elimination of potassium.

Pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of Gelaspan in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Due to the limited data available and the possibility of severe anaphylactoid/ anaphylactic reactions with consecutive foetal and neonatal distress, the use of Gelaspan solutions during pregnancy should be restricted to emergency situations.

Breastfeeding

There are no or limited data regarding the excretion of succinylated gelatin in mother's milk, but because of its high molecular weight it is not expected that the milk will contain relevant amounts. Sodium and chloride are normal constituents of the human body and of food. No significant increase in the content of these electrolytes in mother's milk is expected following the use of Gelaspan.

Fertility

There are no data on the effect of Gelaspan on human or animal fertility. However, because of the nature of its constituents it is considered unlikely that Gelaspan will affect fertility.

Dosage

Posology

Dosage and infusion rate are adjusted according to the amount of blood loss and to individual needs for restoration and maintenance of a stable haemody namic situation, respectively. The dose administered is initially 500 to 1000 ml on average, in case of severe blood loss higher doses can be applied.

Adults

In adults, 500 ml is administered at an appropriate rate depending on the haemodynamic status of the patient. In the case of more than 20 per cent blood loss usually blood or blood components should be given in addition to Gelaspan.

Maximum dose:

The maximum daily dose is determined by the degree of haemodilution. Care must be taken to avoid a decrease of haemoglobin or the haematocrit below critical values.

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:

Up to the first 20 of solution should be infused slowly in order to detect anaphylactic /anaphylactoid reactions as early as possible. See also sections 'special warnings and precautions' and 'undesirable effects'.

In severe, acute situations, Gelaspan may be infused rapidly by pressure infusion, 500 ml within 5 – 10 min, until signs of hypovolaemia are relieved..

Paediatric population

The safety and efficacy of Gelaspan in children have not yet been completely established. Therefore, no recommendation on a posology can be made. Gelaspan should only be administered to these patients if the expected benefits clearly outweigh potential risks. In those cases the patient's prevailing clinical condition should be taken into account and the therapy should be monitored especially carefully. (See also section 'special warnings and precautions')

Elderly patients

Caution should be exercised in patients suffering from further diseases like cardiac insufficiency or renal insufficiency that are frequently associated with advanced age (See also section 'special warnings and precautions').

Method of administration

Intravenous use

In case of pressure infusion, which might be necessary in vital emergencies, all air must be removed from the container and the infusion set before the solution is administered.

Overdose

Symptoms

Overdose of Gelaspan may cause hypervolaemia and circulatory overload with a significant fall in haematocrit and plasma proteins accompanied by an electrolyte and acid base imbalance. This may be associated with consecutive impairment of heart and lung function (pulmonary oedema).

Symptoms of circulatory overload are e.g. headache, dyspnoea, and jugular vein congestion.

Treatment

In case circulatory overload appears, the infusion must be stopped and a rapid-acting diuretic should be given. If an overdose occurs, the patient should be treated symptomatically with monitoring of electrolytes.

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 < 1/1,000)
Very rare: (< 1/10,000)
Not known: (cannot be estimates from the available data)

As with other colloidal plasma substitutes, side effects can occur during and after the use of Gelaspan. These will usually involve anaphylactic/anaphylactoid reactions of varying severity. (See "Special warnings and precautions for use")

Immune system disorders

Rare: Anaphylactic/anaphylactoid reactions up to shock

In the event of an anaphylactoid reaction, the infusion must be discontinued immediately and the usual emergencytreatment given.

Blood and lymphatic system disorders

Very common: Decreased haematocrit and reduced concentration of plasma proteins.

Common (depending on the administered dose): Relatively large doses of Gelofusine Gelaspan result in dilution of coagulation factors and can therefore affect blood coagulation. Prothrombin time can be increased and activated partial thromboplastin time (aPTT) can be prolonged after administration of large doses of Gelofusine Gelaspan. See "Special warnings and precautions for use".

Cardiac disorders

Very rare: Tachycardia

Vascular disorders

Very rare: hypotension

General disorders and administration site conditions

Very rare: fever, chills

Gastrointestinal disorders

Unknown: nausea, vomiting, abdominal pain

Investigations

Unknown: oxygen saturation decreased

Note:

Patients should inform their doctor or pharmacist if they notice any side effect not mentioned in this leaflet.

Expiry date

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

Instructions for storage / disposal / use / handling

Do not store above 30 °C. Do not freeze.

No special requirements for disposal

The product is supplied in containers for single use only. Unused contents of an opened container must be discarded and not stored for later use. Do not reconnect partially used containers.

Only to be used if solution is clear, colourless or slightly yellowish and free of precipitate and the container and its closure are undamaged.

Use immediately after connecting container to the giving set.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

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