

NAME OF THE MEDICINAL PRODUCT

Gelaspan solution for infusion

COMPOSITION

1 000 ml of solution for infusion contain:

Succinylated gelatine (=modified fluid gelatine)	40.0 g
Molecular weight (weight average):	26 500 Da
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
<i>Electrolyte concentrations:</i>	
Sodium	151 mmol/l
Chloride	103 mmol/l
Potassium	4 mmol/l
Calcium	1 mmol/l
Magnesium	1 mmol/l
Acetate	24 mmol/l
<i>Excipients:</i>	
Sodium hydroxide (for pH adjustment)	
Hydrochloric acid, diluted (for pH-adjustment)	
Water for injections	

THERAPEUTIC 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 of hypotension caused by relative hypovolaemia during induction of epidural or spinal anaesthesia or 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. heart-lung machine).

CONTRAINDICATIONS

Hypersensitivity to gelatin-containing solutions or to any of the excipients; hypersensitivity to galactose- α -1,3-galactose (alpha-Gal) or known allergy to red meat (mammal meat) and offal;

hypervolaemia; hyperhydration; acute congestive cardiac failure.

UNDESIRABLE EFFECTS

Summary of the safety profile:

Adverse drug reactions can occur during and after the use of Gelaspan. These will usually involve anaphylactic/anaphylactoid reactions of varying severity, notably for hypersensitivity to galactose- α -1,3-galactose (alpha-Gal) and allergy to red meat and offal).

Undesirable effects are listed according to their frequencies as follows:

Very common:	($\geq 1/10$)
Common:	($\geq 1/100$ to $< 1/10$)
Rare:	($\geq 1/10\ 000$ to $< 1/1000$)
Very rare:	($< 1/10\ 000$)
Not known:	(cannot be estimated from the available data)

Immune system disorders

Rare: Anaphylactic/anaphylactoid reactions up to shock

Cardiac disorders

Very rare: Tachycardia

Vascular disorders

Very rare: Hypotension

General disorders and administration site conditions

Very rare: Fever, chills

Gastro intestinal disorders

Unknown: Nausea, vomiting, abdominal pain

Investigations

Unknown: Oxygen saturation decreased

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 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 Gelaspan.

Information on particular undesirable effects:

Mild anaphylactoid reactions include:

Generalised erythema, urticaria, periorbital oedema, or angiooedema.

Moderate anaphylactoid reactions include:

Dyspnoea, stridor, wheeze, nausea, vomiting, dizziness (presyncope), diaphoresis, chest or throat tightness, or abdominal pain.

Severe anaphylactoid reactions include:

Cyanosis or SaO₂ ≤ 92% at any stage, hypotension (systolic blood pressure < 90 mmHg in adults), confusion, collapse, loss of consciousness, or incontinence.

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

Paediatric population:

There are no data relating to a special pattern or incidence of adverse reactions in paediatric patients.

WARNINGS

Keep out of the sight and reach of children. For single use only. Use only clear solution ensuring it is practically partically free, from intact containers.

Expel all air from the container and the infusion set 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 information and availability.

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