NAME OF THE MEDICINAL PRODUCT

Gelofusine, solution for infusion

COMPOSITION

1000 ml Gelofusine contain:

Succinylated gelatin (=modified fluid gelatin) (Molecular weight, weight average: 26 500 Dalton)	40.0	g
Sodium chloride	7.0	g
Electrolyte content:		
Sodium	154	mmol
Chloride	120	mmol

Excipients:
Sodium hydroxide (for pH-adjustment), hydrochloric acid (for pH-adjustment), water for injections.

THERAPEUTIC INDICATIONS

Gelofusine is a colloidal plasma volume substitute for:
Treatment of relative or absolute hypovolaemia and shock.
Prophylaxis 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. 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; hypervolemia, hyperhydration; acute congestive cardiac failure.

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 < 1/1000)
Very rare: (<1/10 000)
Not known: (cannot be estimated from the available data)

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

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 Gelofusine 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.

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 $SaO_2 \leq 92\%$ 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. Discard unused contents.
Only to be used if solution is clear, colourless or slightly yellowish and container and closure are undamaged. Use immediately after first opening. Expel all air 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 availability and information.

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