Directions for use
Read carefully!

Gelofusine®

Composition
1000 ml solution for infusion contains:

Active ingredients

Succinylated gelatin (Modified fluid gelatin)		40.00 g
Weight average molecular weight ($\overline{M}_w$)	30 000	
Number average molecular weight ($\overline{M}_n$)	23 200	
Sodium chloride		7.01 g

Excipients:
Sodium hydroxide, water for injections

Electrolyte concentrations

Sodium	154 mmol/l
Chloride	120 mmol/l

Physico-chemical characteristics

Theoretical osmolarity:	274 mOsm/l
pH	7.1 – 7.7
Gel point	⩽ 3°C

Pharmaceutical form
Solution for infusion.

Pharmaco-therapeutic group
Colloidal plasma volume substitute.

Therapeutic indications
As a colloidal volume substitute for
- prophylaxis and treatment of absolute and relative hypovolaemia (e.g. following shock due to haemorrhage or trauma, peri-operative blood losses, burns, sepsis)
- prophylaxis of hypotension (e.g. in connection with induction of epidural or spinal anaesthesia)
- haemodilution
- extra-corporeal circulation (heart-lung machine, haemodialysis)

Contraindications
Gelofusine® must not be administered in cases of
- know hypersensitivity to gelatin
- hypervolaemia
- hyperhydration
- severe cardiac insufficiency
- severe disturbance of blood coagulation

Gelofusine® may only be administered with great caution in cases of
- hypernatraemia, since additional sodium is administered with Gelofusine®;
- states of dehydration, since in such cases it is primarily the fluid balance that requires correction;
- disturbance of blood coagulation, since administration leads to dilution of coagulation factors;
- renal insufficiency, since the normal excretion route may be impaired;
- chronic liver disease, since here the synthesis of albumin and coagulation factors can be affected and administration brings about a further dilution.

Precautions for use
The following precautions must be taken into account:
Electrolytes should be substituted as required.

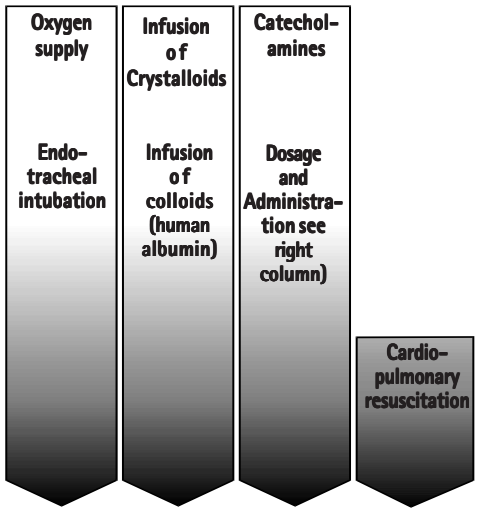
Necessary monitoring
It is necessary to monitor the serum ionogram and fluid balance. This is particularly the case in hypernatraemia, states of dehydration and renal insufficiency.
In cases of blood coagulation disturbances and chronic liver disease the coagulation parameters and serum albumin should be monitored.
Because of the possibility of allergic (anaphylactic/anaphylactoid) reactions, appropriate monitoring of patients is necessary.

General guidelines concerning the prophylaxis and treatment of allergic (anaphylactic/anaphylactoid) side effects
- Adequate information should be available to doctors and nursing staff concerning the type and severity of reactions attributable to colloidal volume substitutes,
- Equipment and medicaments for resuscitation must be readily available,
- Careful observation of the patient during infusion and particularly during administration of the first 20 - 30 ml.
- The infusion must be stopped immediately at the first signs of side effects. (see table below)

There is no known test for advance identification of patients liable to experience anaphylactoid or anaphylactic reactions.
The course of an intolerance reaction cannot be predicted. Allergic (anaphylactic/anaphylactoid) reactions to gelatin solutions can be both histamine-mediated and histamine-independent. The release of histamine can be inhibited prophylactically with H_1 and H_2-blockers. The prophylactic administration of corticosteroids has not proved useful.
Adverse reactions can occur both in conscious and anaesthetised patients. However, in the acute phase of hypovolaemic shock, so far allergic (anaphylactic/anaphylactoid) reactions have never been observed.

Emergency Treatment – Anaphylactic/Anaphylactoid Reactions

Intensity/ Grade	Manifestation	Clinical signs & symptoms	Measures & drug therapy
Ia	localized skin reaction	localized erythema	
Ib	mild systemic reaction	anxiety, headache, flushing, generalized urticaria, mucosal edemas, paraesthesia	• H_1/H_2-antihistamines as appropriate
II	cardiovascular and/or pulmonary and/or gastrointestinal reaction	tachycardia, fall in blood pressure dyspnoea, beginning of bronchospasms nausea, vomiting	• epinephrine, e.g. inhaled epinephrine or 0.5-1.0 ml epinephrine 1:10,000 slowly i.v. • corticosteroids i.v. as appropriate • H_1/H_2-antihistamines as required
III	alarming systemic reaction	severe hypotension and shock severe dyspnoea and bronchospasm	• catecholamines, e.g. 1 ml epinephrine 1:10,000 slowly i.v., repeated doses if necessary up to a total dose of 10 ml • in cases of severe bronchocon - striction: theophyllin i.v. • corticosteroids i.v. as appropriate • H_1/H_2-antihistamines as required
IV	life-threatening systemic reaction	respiratory and cardiac arrest	• basic life support • advanced life support - catecholamines, e.g. 10 ml epinephrine 1:10,000 i.v., repeated if necessary • consider other drugs like: - noradrenaline, dopamine, dobutamine - sodium bicarbonate



(modified from Ahnefeld et al., 1994, Results of a consensus conference: Anaesthesist 43, 211-222)

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Effect on clinical-chemical parameters
Clinical-chemical parameters may be affected. Thus, the results of the following laboratory determinations can be elevated: blood sedimentation rate, specific gravity of the urine and non-specific protein determinations (e.g. by the biuret method).

Forms of interaction with other medicinal products
Incompatibilities can occur on mixing with other medicaments.

Special warnings

Paediatric use
No experience is available concerning administration in children less than one year of age.

Use in pregnancy and lactation
There is no evidence of an embryotoxic effect of Gelofusine®. However, because the possibility of an allergic (anaphylactic/anaphylactoid) reaction cannot be excluded, administration should only be carried out during pregnancy after critical evaluation of the risks and benefits.
No information is available concerning the passage of Gelofusine® into mother's milk.

Dosage
Dosage, infusion rate and duration of administration depend upon individual requirements and should be adjusted to the current requirement by monitoring the usual circulation parameters (e.g. blood pressure).
In order to allow early recognition of the allergic (anaphylactic/anaphylactoid) reactions described under undesirable effects, the first 20 - 30 ml should be infused slowly with the patients under close observation.

The following dosage recommendations are a guideline and apply to adults:

Indications	**Average dosage**
Prophylaxis of hypovolaemia and hypotension, treatment of mild hypovolaemia (e.g. slight losses of blood and plasma)	500 - 1000 ml
Treatment of severe hypovolaemia	1000 - 2000 ml
In emergencies with vital indications	500 ml as rapid infusion (under pressure), then after improvement of circulation parameters, further infusion to commensurate with the volume deficit
Haemodilution (isovolaemic)	Gelofusine® administration corresponds to the volume of blood removed. As a rule however, this should be no more than 20 ml/kg body weight per day.
Extra-corporeal circulation	Depending on the circulation system used, but usually 500 to 1500 ml

In the case of patients with blood coagulation disturbances, renal insufficiency and chronic liver disease it is recommended to adjust the dosage according to the individual clinical situation, taking into account results of clinical-chemical investigations.

Maximum daily amount
The therapeutic limit is set by the dilution effect. Erythrocyte replacement or the administration of whole blood should be considered at the latest when the haematocrit falls below 25% (30% in the case of patients at cardiovascular or pulmonary risk).

Maximum infusion rate
The maximum infusion rate depends on the particular cardio-circulatory situation.

Note
Gelofusine should be previously warmed to body temperature if it is to be administered by pressure infusion (pressure cuff, infusion pump).

Route of administration I.V.

Overdose
Overdosage of volume replacement solutions may lead to unintended hypervolaemia with consecutive impairment of heart and lung function. As soon as symptoms of circulatory overload begin to manifest, e.g. dyspnoea, jugular vein congestion, the infusion must be stopped immediately.

Undesirable effects
As with all colloidal volume substitutes, allergic (anaphylactoid or anaphylactic) reactions of varying severity can occur after infusion of Gelofusine®. These reactions manifest themselves as skin reactions (urticaria) or can result in a flushing of the face and neck. In rare cases, a drop in blood pressure, shock or cardiac and respiratory arrest could occur.
Details of emergency treatment are given under "Precautions for use and special warnings" in the section **"General guidelines concerning the prophylaxis and treatment of allergic (anaphylactic/anaphylactoid) side effects"**

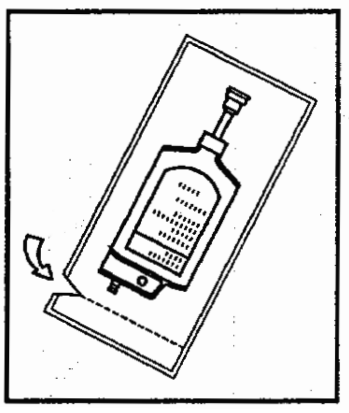
Note
Patients are encouraged to report any adverse reactions they experience which are not mentioned in this leaflet to the doctor or the pharmacist.

Shelf Life
The product must not be used beyond the expiry date stated on the label. The product should not be used if the solution is not clear or the container or its closure show visible signs of damage.

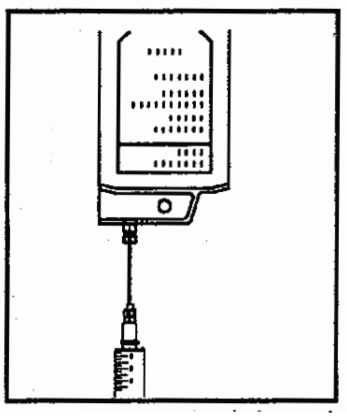
Presentation
500 ml and 1000 ml plastic container (without infusion set)
500 ml PVC bag

Method of administration
In the special case of rapid infusion under external pressure which may be necessary in emergency situations, before starting the infusion, all air must be removed from containers with air space inside, as otherwise there is a risk of producing air embolism during the infusion.

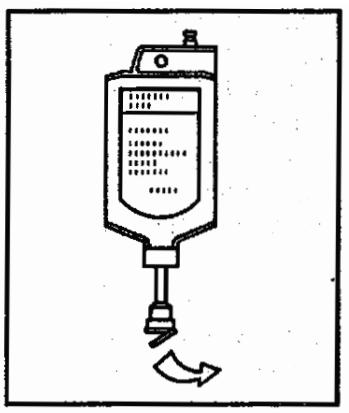
For PVC bag
Handling Instructions



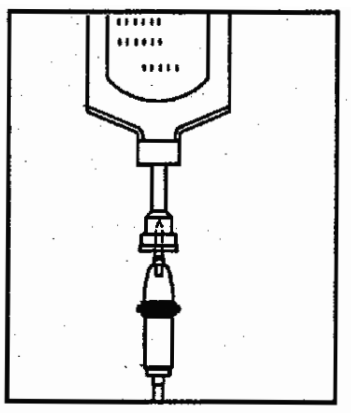
Remove protective wraping by tearing it off in a horizontal direction from the indentation at the sice.



Additives can be injected through the injection port if neccessary. Swab the injection port and inject through the latex piece.
Mix contents thoroughly.



Remove protective cap to exqose the infusion area.



Insert spike of administration set using aseptc procedures.

Product registration holder and manufactured by:
B. Braun Medical Industries Sdn. Bhd.
(Company No. 19051-M)
11900 Bayan Lepas, Penang, Malaysia.

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