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Directions for use
Read carefully!

Modified Fluid Gelatin

Gelofusine®
Plasma Substitute for Intravenous Infusion

Each 100 mL contains:		
Modified Fluid Gelatin	4 g	
Sodium Chloride	701 mg	
Sodium Hydroxide	136 mg	
Weight average Molecular weight ($\overline{M}_w$) 30,000 Number average Molecular weight ($\overline{M}_n$) 23,200		
Water for Injections		100 mL

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

Modified Fluid Gelatin (Gelofusine®) must not be administered in cases of
- know hypersensitivity to gelatin
- hypervolaemia
- hyperhydration
- severe cardiac insufficiency
- severe disturbance of blood coagulation

Modified Fluid Gelatin (Gelofusine®) may only be administered with great caution in cases of
- hypernatraemia, since additional sodium is administered with Modified Fluid Gelatin (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	Stop infusion and Oxygen supply Endo-tracheal intubation Infusion of Crystalloids Infusion of colloids (human albumin) Catechol-amines Dosage and Administration see right column) Cardio-pulmonary resuscitation	
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)

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 Modified Fluid Gelatin (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 Modified Fluid Gelatin (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)	Modified Fluid Gelatin (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.

Cautions

Foods, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA:
www.fda.gov.ph

Seek medical attention immediately at the first sign of any adverse drug reaction.

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Note

Modified Fluid Gelatin (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 Modified Fluid Gelatin (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.

Storage

Store at temperature below 25°C.

Presentation

500 mL plastic container (with and without infusion set).

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.

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