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# Directions for use
# Read carefully!

# Gelofusine®

# جیلوفیوژن
## برائے انٹراوینس انفیوژن

**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 |
| Sodium hydroxide | | 1.36 g |
| *Excipients* | | |
| Water for Injections | | |

**Electrolyte concentrations**

| | |
|---|---|
| Sodium | 154 mmol/l |
| Chloride | 120 mmol/l |

**Physico-chemical characteristic**

| | |
|---|---|
| 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**
Gelofusine® is a colloidal volume substitute for
- Treatment of absolute and relative 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. heart-lung machine).

**Contraindications**
Gelofusine® must not be administered in cases of
- know hypersensitivity to gelatin
- 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

**Gelofusine® should only be administered with great caution in cases of**
- 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 severe hypernatraemia
- with severe hyperchloraemia
- having oedema with water/salt retention
- with major blood coagulation disorders
- of advanced age (elderly patients) as those are more prone to develop disorders such as cardiac or renal insufficiency

**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 H1 and H2-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** | |
| 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<br>dyspnoea, beginning of bronchospasms<br>nausea, vomiting | **Oxygen supply** **Endo-tracheal intubation** | • epinephrine, e.g. inhaled epinephrine or 0.5-1.0 ml epinephrine 1:10,000 slowly i.v.<br>• corticosteroids i.v. as appropriate<br>• $H_1/H_2$-antihistamines as required |
| III | alarming systemic reaction | severe hypotension and shock<br>severe dyspnoea and bronchospasm | **Infusion of Crystalloids** **Infusion of colloids (human albumin)** | • catecholamines, e.g. 1 ml epinephrine 1:10,000 slowly i.v., repeated doses if necessary up to a total dose of 10 ml<br>• in cases of severe bronchocon - striction: theophyllin i.v.<br>• corticosteroids i.v. as appropriate<br>• $H_1/H_2$-antihistamines as required |
| IV | life-threatening systemic reaction | respiratory and cardiac arrest | **Catechol-amines** **Dosage and Administration see right column)** **Cardio-pulmonary resuscitation** | • basic life support<br>• advanced life support - catecholamines, e.g. 10 ml epinephrine 1:10,000 i.v., repeated if necessary<br>• 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**
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

**Special warnings**

*Paediatric use*
There is insufficient experience with the use of Gelofusine® in children. Therefore, Gelofusine® should only be administered to these patients if the expected benefits clearly outweigh potential risks

*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

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

**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 maximum daily dose is determined by the degree of haemodilution. Care must be taken to avoid a decrease of the haemoglobin or 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.

**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** Intravenous use

**Overdose**
Overdosage of Gelofusine® may lead to unintended 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. As soon as symptoms of circulatory overload begin to manifest, e.g. dyspnoea, jugular vein congestion, the infusion must be stopped immediately, and a rapid-acting diuretic should be given. If an overdose occurs, the patient should be treated symptomatically with monitoring of electrolytes

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**Undesirable effects**
As with all colloidal volume substitutes, allergic (anaphylactoid or anaphylactic) reactions of varying severity can occur during 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.

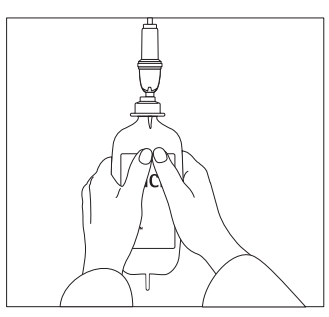
**Presentation**
500 ml plastic container

## احتیاطی تدابیر :

تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔
دوا کو 25°C سے کم درجہ حرارت پر رکھیں۔

**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.

## Handling Instructions Ecoflac® plus



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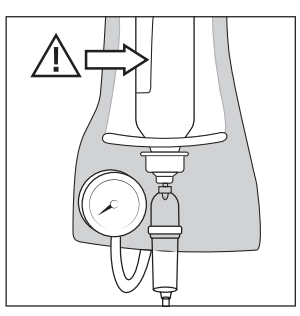
**Pressure infusion**
- Insert infusion set.
- Hold container upright.
- Leave clamp open, expel air from container and fill half of drip chamber.
- Turn container and expel air from infusion device.
- Close clamp.



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- Place container in pressure cuff.
- Build up pressure.
- Open clamp and start infusion.

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