

Overdose

If overdose occurs, stop the infusion and give a fast acting diuretic.

In case of overdose, the patient should be treated symptomatically and electrolytes should be monitored.

Special precautions for disposal and other handling

Aseptic handling of the solution must be ensured

Check that the container is intact and the solution clear before use.

Discard any container which is damaged or from which fluid has been removed.

The residual volume of solution left after infusion must never be used again later.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

amount expressed as anhydrous gelatin 3.0000 g
Sodium chloride 0.5382 g
Magnesium chloride hexahydrated 0.0305 g
Potassium chloride 0.0373 g
Sodium (S)-lactate solution
amount expressed as sodium lactate 0.3360 g
per 100 ml of solution for infusion

* partially hydrolysed and succinylated

The other ingredients are: sodium hydroxide; succinic anhydride as succinic acid; hydrochloric acid, concentrated; water for injections.

Ionic formula:

Sodium = 150 mmol/l
Potassium = 5 mmol/l
Magnesium = 1.5 mmol/l
Chloride = 100 mmol/l
Lactate = 30 mmol/l

Total osmolality: 295 mOsm/kg

pH: 5.8 to 7.0

What GELOPLASMA, solution for infusion, looks like and contents of the pack

GELOPLASMA, solution for infusion is presented in 500 ml PVC bag with overwrap (box of 1 and 15) or **Freeflex** (polyolefine) bag with overwrap (box of 20).

Not all pack sizes may be marketed

Marketing Authorisation holder and ManufacturerMarketing Authorisation Holder

Fresenius Kabi Limited
Cestrian Court,
Eastgate Way, Manor Park,
Runcorn, Cheshire,

Manufacturer

Fresenius Kabi France
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27400 Louviers
France

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	GELOPLASMA Infusionslösung
Czech	Republic: Geloplasma, infuzní roztok
Estonia:	Geloplasma, infusioonilahus
Finland:	GELOPLASMA infusiooneste, liuos
France:	PLASMION, solution pour perfusion
Germany:	Geloplasma Infusionslösung
Hungary:	Geloplasma oldatos infúzió
Ireland:	GELOPLASMA, solution for infusion
Italy:	Infuplas soluzione per infusione
Latvia:	Geloplasma šķīdums infūzijām
Lithuania:	GELOPLASMA infuzinis tirpalas
Norway:	Geloplasma infusjonsvæske, oppløsning
Poland:	GELOPLASMA
Portugal:	Geloplasma, Solução para perfusão
Romania:	Geloplasma 3 g/100 ml soluție perfuzabilă
Slovakia:	GELOPLASMA, infúzný roztok
Slovenia:	Geloplasma raztopina za infundiranje
Spain:	Geloplasma, solución para perfusión
UK:	GELOPLASMA solution for infusion

This leaflet was last revised on January 2016.

Package leaflet: Information for the user**GELOPLASMA**
solution for infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GELOPLASMA, solution for infusion, is and what it is used for
2. What you need to know before you use GELOPLASMA, solution for infusion
3. How to use GELOPLASMA, solution for infusion
4. Possible side effects
5. How to store GELOPLASMA, solution for infusion
6. Contents of the pack and other information

1. What GELOPLASMA, solution for infusion, is and what it is used for

GELOPLASMA is a solution for intravenous infusion. It contains gelatin, which belongs to a group of medicines known as plasma volume expanders. Plasma volume expanders work by increasing the fluid in your blood stream, which helps keep your blood stream and therefore your blood pressure stable.

This medicine is an emergency treatment in case of low blood volume in the following situations:

- Haemorrhage (*bleeding*), dehydration, capillary leak (*increased microvascular permeability*), burns;
- severe vasodilatation (*widening of blood vessels*) from traumatic, surgical, septic or toxic origin.

It is also used in the treatment of low blood volume associated with hypotension (*low blood pressure*) in the context of severe vasodilatation related to the effects of hypotensive drugs, notably during anesthesia.

2. What you need to know before you use GELOPLASMA, solution for infusion
Do not use GELOPLASMA, solution for infusion:

- if you are allergic to the active substances or to any other ingredients of this medicine (listed in section 6);
- if you have an excess of fluid in the body;
- if you have hyperkalaemia (excess of potassium in the blood);
- if you have a high accumulation of alkaline substance (e.g. bicarbonate, lactate) in your blood and body fluid;
- if you are at the end of pregnancy (during labour/delivery): see "Pregnancy, breast-feeding and fertility" section.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using GELOPLASMA, solution for infusion.

- This solution must not be given by intramuscular injection.
- This solution may cause accumulation of alkaline substances in your blood due to the presence of lactate ions.
- This solution may not have its alkalinising action in cases of impaired liver function since lactate metabolism may be disturbed.
- GELOPLASMA must not be administered at the same time as blood or its derivatives (packed cells, plasma and plasma fractions) but using two separate infusion systems.

- Determination of blood group and any laboratory blood tests are possible if you have received up to 2 litres of liquid gelatin but it may be preferred to draw the sample for these tests **before** the infusion of this solution.
- Because of the possibility of allergic reaction, appropriate monitoring is necessary. In case of an allergic reaction, the infusion must be stopped immediately and appropriate treatment given.
- Use of this solution **requires clinical and laboratory monitoring** of:
 - blood pressure, and possibly central venous pressure (measured by a catheter in a vein that leads directly to the heart);
 - urine output;
 - haematocrit (blood volume) and electrolytes (*ions present in the blood*).

Especially in the following situations:

- congestive heart failure (*a condition in which the heart cannot pump enough blood to the body's other organs*);
- respiratory functional impairment;
- severe kidney disease;
- oedema with water/salt retention;
- circulatory overload (*excess of intravascular liquid*);
- treatment with corticosteroids or their derivatives;
- blood clotting disorders.

Other medicines and GELOPLASMA, solution for infusion

- Use of other intravenous medicines at the same time as **GELOPLASMA** is inadvisable.
- Since this solution contains potassium, it is preferable to avoid using potassium and medicinal products that may cause excess of potassium in blood.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

GELOPLASMA, solution for infusion, with food and drink

Not applicable.

Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

There are no or limited amount of data from the use of GELOPLASMA, solution for infusion, in pregnant women. GELOPLASMA, solution for infusion, must only be given if clinically necessary. Your physician has assessed the benefits versus the potential risk to the baby.

Breast-feeding

It is unknown whether GELOPLASMA, solution for infusion, is excreted in human breast milk. A risk to the baby cannot be excluded.

Fertility

There are no data on the effects of GELOPLASMA, solution for infusion, on human or animal fertility.

Driving and using machines

Not relevant.

GELOPLASMA, solution for infusion, contains:

This medicine contains **5 mmol of potassium** per litre. Patients with reduced kidney function or patients on controlled potassium diet should take this information into account.

This medicine contains **150 mmol of sodium** per litre. Patients on controlled sodium diet should take this information into account.

3. How to use GELOPLASMA

*Always use **this medicine** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.*

You will receive your medicine by infusion (intravenous drip). A pump can be used to increase the rate of infusion.

The rate of infusion, along with the volume infused, will depend on your specific requirements.

The quantity administered is 500 to 1000 ml on average (1 to 2 bags) sometimes more.

As a general rule, in adults and children weighing more than 25 kg, 500 ml (1 bag) is administered at an appropriate infusion rate.

If there is a blood loss of more than 1.5 litres in an adult, blood is generally administered as well as GELOPLASMA, solution for infusion.

Tests may be carried out throughout your treatment to ensure that your blood pressure, blood and coagulation parameters are controlled.

If you have been given more GELOPLASMA, solution for infusion, than you should:

Higher doses may cause your blood volume to be excessive.

Increased pressure in the pulmonary circulation leads to leakage of fluid into the extravascular space and may cause fluid on the lungs (*symptoms of breathlessness*).

If overdose occurs, the infusion will be stopped immediately and a quick active diuretic (*drug increasing the flow of urine from your body*) will be given.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

Rare (may affect up to 1 in 1,000 people):

- Anaphylactic shock (severe allergic reaction);
- Allergic skin reaction.

If you notice these effects, please inform your doctor immediately.

Very rare (may affect up to 1 in 10,000 people):

- Decrease of blood pressure;
- Slowing of heart rate;
- Breathing difficulties;
- Fever, chills.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly:

For UK - via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

For Ireland - HPRA Pharmacovigilance

Earlsfort Terrace - IRL - Dublin 2

Tel: +353 1 6764971 - Fax: +353 1 6762517 - Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store GELOPLASMA, solution for infusion

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not freeze.

Do not store in a refrigerator.

Once opened: use immediately, discard any unused portion.

Do not use this medicine if you notice:

- that the container is damaged,
- that the solution is not clear,
- that fluid has been removed from the bag.

6. Contents of the pack and other information

What GELOPLASMA, solution for infusion, contains

The active substances are:

Modified liquid gelatin*

The following information is intended for healthcare professionals only:

Posology and method of administration

Posology

Dosage volume and rate of administration depend upon the individual patient status, circumstances and response to vascular replacement.

Modified liquid gelatin is given by IV infusion (drip infusion). The infusion rate can be increased using a pump.

The dose and infusion rate depend upon the patient's needs and blood volume to be replaced and haemodynamic status of the patient.

The dose administered is 500 to 1000 ml on average (1 to 2 bags), sometimes more.

As a general rule, in adults and children weighing more than 25 kilos, 500 ml (1 bag) is administered at an appropriate rate depending on the status of the patient. The infusion rate can be increased in case of severe haemorrhage.

If there is blood/fluid loss in excess of 1.5 litres in the adult (i.e. greater than 20% of blood volume) blood should usually be administered as well as GELOPLASMA, solution for infusion. The haemodynamic, haematological and coagulation system should be monitored.

Paediatric population

See above.

Method of administration

The solution is administered intravenously.

Special warnings and special precautions for use

Warnings

This solution must not be given by intramuscular injection.

This liquid gelatin solution must not be infused at the same time as blood or its derivatives (packed cells, plasma and plasma fractions) but using two separate infusion systems.

Determination of blood group, irregular antigens and any laboratory blood tests are possible in patients who have received up to 2 litres of liquid gelatin, though interpretation is hampered by haemodilution and it may be preferred to draw the sample for these tests **before** the infusion of liquid gelatin

Precautions

Use of this solution requires clinical and laboratory monitoring of the patient's status:

- blood pressure, and possibly central venous pressure;
- urine output;
- haematocrit and electrolytes.

Especially in the following situations:

- congestive heart failure;
- pulmonary functional impairment;
- severely impaired renal function;
- oedema with water/salt retention;
- circulatory overload;
- treatment with corticosteroids and their derivatives;
- major coagulation disturbances.

The haematocrit should not fall below 25%; in elderly patients it should not fall below 30%. **Blood coagulation disorders caused by dilution of coagulation factors should be avoided.**

If more than 2000 to 3000 ml of GELOPLASMA, solution for infusion, are infused pre-and intra-operatively, it is recommended that the serum protein concentration be checked post-operatively, especially if there are signs of tissue oedema.