

Package leaflet: Information for the user

Gelofusine 40 mg/ml solution for infusion

Succinylated gelatin (modified fluid gelatin)

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 any further questions, ask your doctor or 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What Gelofusine is and what it is used for

Gelofusine is a so-called plasma volume substitute. This means, it replaces fluid lost from the circulation.

Gelofusine is used to replace blood and body fluid, which have been lost following, for example, an operation, an accident or a burn. It may be combined with blood transfusions, if necessary.

It may also be used for

- filling up the circulating blood volume during use of the heart-lung machine or artificial kidney.

2. What you need to know before you use Gelofusine

Do not use Gelofusine

- if you are allergic to gelatin or any of the other ingredients of this medicine (listed in section 6).
- if your circulating blood volume is too large
- if you have heart failure

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using Gelofusine.

Please inform your doctor

- if you are suffering from allergic diseases such as asthma, because you may be at a greater risk to experience an allergic reaction.

Your doctor will take special care about your situation if you suffer from:

- heart problems

- high blood pressure
- water on your your lungs
- severe kidney problems.

Giving large amounts of liquids through an intravenous drip may worsen your condition.

Your doctor will also exercise caution

- if your blood clotting is severely impaired
- if you retain water and salt, which may be associated with tissue swelling

All plasma substitutes carry a slight risk of allergic reactions that are mostly mild or moderate but can in very few cases also become severe. Such reactions are assumed to be more frequent in patients with known allergic conditions such as asthma. For that reason you will be under close observation by a health professional, especially at the beginning of the infusion.

While receiving Gelofusine, your blood composition will be monitored.

This medicinal product contains 154 mmol/l sodium. To be taken into consideration by patients on a controlled sodium diet.

Other medicines and Gelofusine

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

In particular your doctor should know if you are taking or receiving medicines that make you retain sodium (e.g. cortisones).

Pregnancy and 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

If you are pregnant, please inform your doctor. Due to possible allergic reactions the use of this medicine should be avoided during pregnancy. However your doctor may give you this medicine if your clinical condition requires treatment with Gelofusine.

Breast-feeding

If you are breast-feeding, please inform your doctor. It is not known if Gelofusine passes into breast-milk. Your doctor will decide to discontinue breast-feeding or to discontinue/abstain from Gelofusine therapy taking into account the benefit of breast feeding for your child and the benefit of therapy for you.

Driving and using machines

Not applicable for this product. Gelofusine is normally given to immobile patients in a controlled setting (e.g. emergency treatment, acute treatment in a hospital or a day therapy unit) and this excludes the likelihood of driving and using machines.

3. How to use Gelofusine

Gelofusine is given intravenously, i.e. by a drip.

Adults

How much you are given and for how long will depend on how much blood or fluid you have lost and on your condition.

Use in children and adolescents

There is only little experience of the use of Gelofusine in children. Your doctor will only administer this medicine to your child if he/she considers it essential for your child's recovery. In those cases the clinical condition or your child will be taken into account and his/her therapy will be monitored especially carefully.

The doctor will carry out tests (on your blood and blood pressure, for example) during your treatment, and the dose of Gelofusine will be adjusted according to your needs. If necessary you may also receive blood or packed red blood cells.

The doctor will give you the first 20-30 ml of this medicine slowly in order to detect an allergic reaction as early as possible.

In case of pressure infusion, all air must be removed from the container and the infusion set before the solution is administered.

If you use more Gelofusine than you should

An overdose of Gelofusine may cause too high blood volume (hypervolaemia) circulatory overload and imbalances of your blood composition.

You may notice the following symptoms:

- impairment of heart-and lung function
- headache, difficulties to breathe, congestion of blood in the jugular vein

If an overdose occurs your doctor will give you any necessary treatment.

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

4. Possible side effects

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

The possible side effects are listed according to their frequency, using the following terms:

Uncommon: affecting 1 to 10 treated patients of 1,000

Rare: affecting 1 to 10 treated patients of 10,000

Very rare: affecting less than 1 treated patient of 10,000

The following side effects may be serious. If any of the following side effects occur, stop using this medicine and consult a doctor immediately:

Rare:

- allergic skin reactions such as hives or nettle rash
- other allergic (anaphylactoid) reactions, including e.g. . difficulty breathing, wheeze, nausea, vomiting, dizziness, sweating, chest or throat tightness, stomach ache, swelling of neck and face

If an allergic reaction, especially an anaphylactoid reaction occurs your infusion will be stopped immediately and you will be given any necessary treatment.

Very rare:

- quickening of heartbeat
- **severe** allergic reactions such as drop of blood pressure, confusion, involuntary excretion of urine, blue coloration of the skin and mucous membranes (so-called cyanosis) and extremely rare cases of loss of consciousness and collapse

If allergic reactions occur there are established methods of treating them, which would be used immediately by the attending doctor.

Other side effects:

Uncommon:

- short lasting mild rise of body temperature.

Very rare:

- 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 via 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 Gelofusine

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 label and the outer carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not refrigerate or freeze.

Do not use this medicine if you notice

- cloudiness or discoloration of the solution
- leaking of the container.

Previously opened or partly used Gelofusine should be thrown away. Partially used bags should not be reconnected.

6. Further information

What Gelofusine contains

- The active substances are succinylated gelatin (modified fluid gelatin) sodium chloride and sodium hydroxide.

1000 ml of the solution contain:

Succinylated gelatin (modified fluid gelatin)	40.0 g
Sodium chloride	7.01 g
Sodium hydroxide	1.36 g

Electrolyte concentrations

Sodium	154 mmol/l
Chloride	120 mmol/l

- The other ingredient is water for injections.

What Gelofusine looks like and contents of the pack

Gelofusine is a solution for infusion administered through an intravenous drip (a drip into a vein).

It is a clear colourless or slightly yellowish sterile solution.

It comes in:

- polypropylene bags (Ecobag) of 500 ml, available in packs of 20
- polypropylene bags (Ecobag) of 1000 ml, available in packs of 10.

Not all pack sizes may be marketed.

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