

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.
- Prevent low blood pressure (hypotension) which may occur when you are receiving spinal or epidural anaesthesia or due to imminent severe blood loss in a surgical setting.
- Fill up the circulating blood volume during the use of for example heart-lung machine in combination with other fluids for infusion.

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 you are allergic to an allergen called "galactose- α -1,3-galactose (alpha-Gal) or to red meat (mammal meat) and offal
- if your circulating blood volume is too large
- if you have excess fluid in your body
- if you have certain types of heart failure (acute congestive heart failure)

Warnings and precautions

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

Please inform your doctor

- if you suffer from allergic diseases such as asthma. Then you may be at a greater risk of experiencing an allergic reaction.

- In these cases, Gelofusine should not be given to you due to possible cross-reactions:
 - . if you know you have an allergy to red meat (mammal meat) or offal
 - . if you have been tested positive to antibodies (IgE) against the allergen alpha-Gal

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 you have a severe increase of sodium or chloride in your blood
- if you retain water and salt, which may be associated with tissue swelling
- if your blood clotting is severely impaired
- if you are elderly

While receiving Gelofusine, your blood composition will be monitored. If necessary, your doctor may also give you other medications such as salts and fluids.

Children

There is only little experience regarding the use of Gelofusine in children. The doctor will only administer this medicine to children when considered absolutely necessary.

Laboratory test results

Your doctor can take blood or urine samples before giving you Gelofusine. This is because some laboratory test results may be affected after you have received this medication and are therefore unreliable.

Other medicines and Gelofusine

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular your doctor should know if you are taking or receiving medicines that make you retain sodium (e.g. spironolactone, triamterene, amiloride; ACE-inhibitors like captopril or enalapril, corticosteroids like cortisone or non-steroidal anti-inflammatory agents like diclofenac). Concomitant administration with this medicine might lead to swelling of arms, hands, legs and feet (oedema).

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 in emergency situations.

Breast-feeding

If you are breast-feeding, please inform your doctor. There is limited information about excretion of this medicine in breast-milk, but based on its chemical characteristics, it is unlikely that it passes over into breast-milk. Your doctor will decide to discontinue breast-feeding or to discontinue this medicine, taking into account the benefit of breast-feeding for the child and the benefit of therapy for yourself.

Fertility

There are no data on the effect of this medicine on human or animal fertility. However, because of the nature of its constituents it is considered unlikely that it will affect fertility.

Driving and using machines

This medicinal product does not influence your ability to drive or use machines.

3. How to use Gelofusine

Your doctor only will give you Gelofusine if they consider that other products called crystalloids are not sufficient alone.

Your doctor will adjust the dose of Gelofusine carefully in order to prevent fluid overload. This will be done especially if you have problems with your lungs or with your heart or circulation.

Dosage

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.

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.

Use in children

There is only little experience of the use of this medicine in children. Your doctor will only administer this medicine if they consider it essential for the child's recovery. In those cases, the clinical condition will be taken into account and therapy will be monitored especially carefully.

If you use more Gelofusine than you should

An overdose of Gelofusine may cause too high blood volume (hypervolaemia) and fluid overload that may affect your heart and lung function.

You may notice headaches and difficulties breathing.

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

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

4. Possible side effects

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

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.

The following side effects may be serious. If any of the following side effects occur consult a doctor immediately:

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

- allergic (anaphylactic/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 occurs, your infusion will be stopped immediately and you will be given any necessary treatment (see also section 2 “What you need to know before you use Gelofusine, notably for allergies involving the allergen called galactose- α -1,3-galactose (alpha-Gal), red meat and offal).

Other side effects include:

Very common (may affect up to 1 in 10 people):

- a decrease of red blood cells and proteins in your blood

Common (may affect up to 1 in 100 people):

- your blood may not clot as well as before and you may notice more bleeding

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

- quickening of heartbeat
- low blood pressure
- fever, chills.

Unknown (frequency cannot be estimated from the available data):

- feeling sick, being sick, stomach pain
- a decrease of oxygen in your blood which may make you feel dizzy

Additional side effects in children

There are no data relating a difference in side effects in children.

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, Website: www.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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