

Gelofusine®

Succinylated gelatin solution 4% for intravenous infusion

Consumer Medicine Information

1. What is in this leaflet

This leaflet contains some common questions about Gelofusine.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risk of you taking this medicine against the benefits they expect it will have for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

2. What is Gelofusine used for

Gelofusine is a 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 as a result of, for example, an operation, an accident or a burn. It can be used instead of, or as well as, a blood transfusion.

It may also be used for filling up the circulating blood volume during use of the heart-lung machine or artificial kidney.

3. Before you are given Gelofusine

When you must not be given Gelofusine

DO NOT USE GELOFUSINE:

- if you are allergic (hypersensitive) to gelatin or any of the other ingredients of Gelofusine
- if your circulating blood volume is too large
- if you have excess fluid in your body
- if you are at markedly increased risk of bleeding because your blood clotting is severely impaired.

TAKE SPECIAL CARE WITH GELOFUSINE

Please inform your doctor:

- if you have problems with your heart or your kidneys because giving large amounts of liquids through an intravenous drip may affect these organs
- if you are suffering from allergic diseases such as asthma, because you may be at a greater risk to experience an allergic reaction. 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.

TAKING OR USING OTHER MEDICINES

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

PREGNANCY AND BREAST-FEEDING

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or breast-feeding, please inform your doctor. Although you may be given Gelofusine during pregnancy and while breast-feeding, the possible risks and benefits should be considered carefully.

DRIVING AND USING MACHINES

Not relevant. 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.

4. How to use Gelofusine

Gelofusine is given intravenously, i.e. by a drip. How much you are given and for how long will depend on how much blood or fluid you have lost and on your condition.

For children, the doctor will determine the dose especially carefully. A child will receive this medicine only if the doctor considers it essential for his/her recovery.

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 YOU USE MORE GELOFUSINE THAN YOU SHOULD

An overdose of Gelofusine may give rise to circulatory overload and to alterations of your blood salt (electrolyte) levels.

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

5. Possible Side Effects

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

As mentioned above, in rare cases (i.e. in 1 to 10 treated patients in 10,000) mild skin reactions (hives, nettle rash) may occur.

In very rare cases (i.e. in less than 1 treated patient in 10,000) an allergic shock has been observed.

It must be stressed that allergic reactions are extremely rare, but should they occur there are established methods of treating them, which would be used immediately by the attending doctor.

Uncommon side effects (affecting 1 to 10 treated patients in a 1,000) include:

- short lasting queasiness or belly pain
- short lasting mild rise of body temperature.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

6. Storage

Keep out of the reach and sight of children.

Do not use Gelofusine after the expiry date which is stated on the label and the outer carton. The expiry date refers to the last day of that month.

Store below 25°C.

Do not use Gelofusine 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7. Product Description

What Gelofusine looks like

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:

- polyethylene bottles (Ecoflac plus) of 500 ml, available in packs of 10
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- non-PVC plastic bags (Ecobag) of 500 ml, available in packs of 10
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Ingredients

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

1000 ml of the solution contain:

- Succinylated (modified fluid) gelatin 40.0 g
- Sodium 154 mmol/L
- Chloride 120 mmol/L

The other ingredients are water for injections and sodium hydroxide for pH adjustment.

Australian Registration Numbers:

500 mL bottles (Ecoflac plus) ARTG 60644
1000 mL bottles (Ecoflac plus) ARTG 60645
500 mL plastic bags (Ecobag) ARTG 78102
1000 mL plastic bags (Ecobag) ARTG 78103

8. Sponsor Details

B. Braun Australia Pty Ltd

17 Lexington Drive
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Australia
Toll Free Number: 1800 251 705

9. Date of Information

This leaflet was updated in January 2010.