SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Gelofusine® Ecobag

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000 ml of Gelofusine Ecobag contains:

Succinylated Gelatin (Modified Fluid Gelatin)	40.0 g
Electrolytes:	
Na+	154.0 mmol
Cl -	120.0 mmol
Physico-chemical properties.	
Weight average molecular weight (Mw)	30 000 Dalton
Number average molecular weight (Mn)	23 200 Dalton
pH	7.4±0.3
Osmolarity	274 mOsm/l

For excipients see 6.1

3. PHARMACEUTICAL FORM

Solution for infusion
A clear, colourless or slightly yellowish aqueous solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Gelofusine is a colloidal plasma volume substitute for:

- Treatment of relative or absolute hypovolaemia and shock
- Prophylaxis 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)

4.2. Posology and Method of Administration

Gelofusine Ecobag is given intravenously. The volume and the rate of administration will depend upon the condition of the patient. The rate of administration can be increased by the application of pressure to the container or by use of a giving set pump. When given rapidly it should be warmed to no more than 37^0C if possible. In severe, acute blood loss, 500 ml may be given in 5-10 minutes until signs of hypovolaemia are relieved. When large volumes are infused, suitable monitoring should be employed to ensure that an adequate haematocrit is maintained (the haematocrit should not be allowed to fall below 25%) and that dilutional effects upon coagulation are avoided. (Expert haematological advice should be sought, especially in cases of massive blood loss).

For massive fluid loss, Gelofusine Ecobag may be used concomitantly with blood, the rate and amount of which depend upon the clinical condition of the patient. The haemodynamic status of the patient should be monitored.

If blood is to be given at the same time as Gelofusine Ecobag, it can be given through the same giving set since Gelofusine Ecobag has a negligible calcium content and therefore does not clot blood. Gelofusine Ecobag can also be used to reconstitute packed red cells.

NB No distinction between the recommended doses and dosage schedule for adults, children and the elderly is necessary as the rate of administration depends on the condition of the individual patient.

4.3 Contraindications

- Known hypersensitivity to gelatin-containing solutions
- Hypersensitivity to galactose-α-1,3-galactose (alpha-Gal) or known allergy to red meat (mammal meat) and offal (see section 4.4)

4.4 Special warnings and precautions for use

Severe anaphylactic reactions following use of Gelofusine Ecobag occur with a reported incidence of between 1 in 6000 and 1 in 13000 units administered. Such reactions are related to the release of vasoactive substances and can be assumed to be more frequent and particularly hazardous in patients with known allergic conditions such as asthma.

Due to possible cross-reactions involving the allergen galactose-alpha-1,3-galactose (alpha-Gal), the risk of sensitization and consequent anaphylactic reaction to gelatin-containing solutions could be highly increased in patients with history of allergy to red meat (mammal meat) and offal and/or tested positive for anti-alpha-Gal IgE antibodies. Gelatin-containing colloidal solutions should not be used in these patients (see section 4.3)

Treatment: The infusion of Gelofusine Ecobag should be stopped. Further treatment will depend upon the severity of the anaphylactic reaction. Administration of supplemental oxygen; an alternative intravenous fluid; and the parenteral administration of adrenaline (e.g. 0.5 ml of a 1 in 1000 solution intramuscularly, repeated every 5 minutes as necessary, or 5ml of a 1 in 10 000 solution slowly intravenously), and an antihistamine (e.g. chlorpheniramine 10-20 mg slowly intravenously) should be considered.

Gelofusine Ecobag should be given with care to patients who are susceptible to circulatory overloading (e.g. severe congestive cardiac failure or renal failure with oliguria or anuria) since excessive volumes may give rise to circulatory overload and electrolyte imbalance.

Treatment: The infusion should be stopped and the patient treated symptomatically.
Electrolytes should be monitored. If necessary a diuretic may be given to promote fluid loss. Decreased urinary output secondary to shock is not a contra-indication unless there is no improvement in urine output after the initial dose of Gelofusine Ecobag.

4.5. Interactions with other Medicinal Products and other forms of Interaction

None known

4.6 Pregnancy and Lactation

There is very little information available on the use of plasma substitutes in pregnant or lactating women. As with all drugs, the benefits and risks of use should be assessed in the light of the patient's condition. Gelofusine Ecobag may be used in the initial treatment of blood loss during pregnancy where plasma volume replacement is needed.

4.7. Effects on Ability to Drive and Use Machines

Not applicable

4.8 Undesirable effects

In common with other colloidal plasma volume expanders, mild urticarial reactions have been reported.

There have been rare reports of allergic reactions including anaphylactoid reactions following administration of Gelofusine

For treatment of anaphylactic reactions. (see also sections 4.3 and 4.4, notably for hypersensitivity to galactose-α-1,3-galactose (alpha-Gal) and allergy to red meat and offal).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9. Overdose

An overdose of Gelofusine Ecobag may give rise to circulatory overload and electrolyte imbalance (see 4.4 Special Warnings and Precautions for use).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Gelofusine Ecobag is a colloidal plasma volume substitute. When used in the treatment of hypovolaemia it produces significant increases in blood volume, cardiac output, stroke volume, blood pressure, urinary output and oxygen delivery.

Gelofusine Ecobag promotes an osmotic diuresis, thereby helping protect the kidneys from the adverse effects of hypovolaemia.

5.2. Pharmacokinetic Properties

The half life of Gelofusine Ecobag is about 4 hours, with the majority of the dose being eliminated by renal excretion within 24 hours.

5.3. Preclinical Safety Data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections, NaOH for pH adjustment.

6.2. Incompatibilities

There are no known major incompatibilities. Gelofusine Ecobag does not interfere with blood grouping or cross-matching.

6.1. Shelf -Life

Shelf life of the medicinal product as packaged for sale

The shelf-life of Gelofusine Ecobag is 20 months for the 100 ml and 24 months for 250 ml, 500 ml and 1000 ml packs.

Shelf life after first opening the container

Not applicable. Infusion should commence immediately after connecting the container to the giving set.

6.4. Special Precautions for Storage

Dot not store above 25°C
Do not freeze.

6.5. Nature and Contents of Container

Gelofusine Ecobag is available in 100 ml, 250 ml, 500 ml and 1000 ml non PVC.

6.6. Instruction for Use and Handling

The container overwrap is not sterile. If it is damaged, or fluid is present in the space between the wrap and the container, the container should be assumed to be damaged and should therefore be discarded. The entry port area should be disinfected prior to insertion of the giving set.

Only clear solution should be used; it contains no preservative and any unused Gelofusine Ecobag should be discarded once the seal has been opened. Do not reconnect partially used containers.

7. MARKETING AUTHORISATION HOLDER

B Braun Melsungen AG
Carl-Braun-Strasse 1
D-34212 Melsungen
Germany

8. MARKETING AUTHORISATION NUMBER(S)

PL 03551/0047

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05/12/2008

10 DATE OF REVISION OF THE TEXT

26/08/2020