PRESCRIBING INFORMATION

GELOFUSINE®

Presentation:
Sterile 4% w/v succinylated Gelatin (Modified Fluid Gelatin) in Saline

Gelatin (MFG)	40.0 gm/litre	Chloride	125 mmol/litre
Sodium	154 mmol/litre	Av Mw	30,000
Av Mn	22,600	Relative viscosity at 37°C	1.9
pH	7.4±0.3	Colloid osmotic pressure	465 mmH_2O
Osmolarity	279mOsm/litre	Gel point	0°C
Iso-electric point	pH 4.5±0.3		

Description: Gelofusine is prepared by hydrolysis and succinylation of bovine collagen. **Uses.** *Actions:* Gelofusine 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. The half-life of Gelofusine is about 4 hours, with the majority of the dose administered being eliminated by renal excretion within 24 hours. *Indications:* As a plasma volume substitute in the initial management of hypovolaemic shock due to, for example, haemorrhage, acute trauma or surgery, burns, sepsis, peritonitis, pancreatitis or crush injury. **Dosage and Administration.** Gelofusine 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°C if possible. In severe acute blood loss 500ml 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 than 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 may be used concomitantly with blood, the rate and amount of which would 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 it can be given through the same giving set since Gelofusine has a negligible calcium content and therefore does not clot blood. Gelofusine can also be used to reconstitute packed red cells. **Contra-indications, warnings, etc.** Known hypersensitivity to Gelofusine. In common with other colloidal plasma volume expanders, mild urticarial reactions have been reported. Severe anaphylactic reactions following use of Gelofusine 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. *Treatment:* The infusion of Gelofusine 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 (eg 0.5 to 1ml of a 1:1,000 solution intramuscularly, repeated every 15 minutes as necessary, or 5 to 10ml of a 1:100,000 solution slowly intravenously), and an antihistamine (eg chlorpheniramine 10 – 20mg slowly intravenously) should be considered. Gelofusine should be given with care to patients who are susceptible to circulatory overloading (eg 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 contraindication unless there is no improvement in urine output after the initial dose of Gelofusine. **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 may be used in the initial treatment of blood loss during pregnancy where plasma volume replacement is needed. **Pharmaceutical Precautions:** The bottle overwrap is not sterile. If it is damaged, or fluid is present in the space between the wrap and the plastic bottle, the bottle 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. Gelofusine is stable for five years and can be stored at room temperature. Only clear solution should be used; it contains no preservative and any unused Gelofusine should be discarded once the seal has been opened. Although water soluble drugs can be given in Gelofusine, experience is limited. If essential, they may be given through the giving set, close to the intravenous cannula. The small calcium content of Gelofusine does not give rise to clotting in the giving set when citrated blood precedes or follows its administration. **Legal Category:** POM. **Package quantities:** Plastic infusion containers of 500ml. Packs of 10. **Basic NHS Price:** £3.56/500ml unit. **Further information:** Gelofusine promotes an osmotic diuresis, thereby helping protect the kidneys from the adverse effects of hypovolaemia. it does not interfere with blood grouping or cross-matching. **Product licence number:** 0183/5025. **Product licence holder:** Consolidated Chemicals, Ltd, The Industrial Estate, Wrexham, Clwyd LL13 9PS. Manufactured by B. Braun Medical A.G., PO Box 983, CH-9001 St-Gallen, Switzerland. **Name and address of promoter:** B. Braun Medical Ltd, Braun House, 13-14 Farmbrough Close, Aylesbury Vale Industrial Park, Stocklake, Aylesbury, Bucks. HP20 1DQ, England. Tel: 0296 393900, Fax: 0296 435714.
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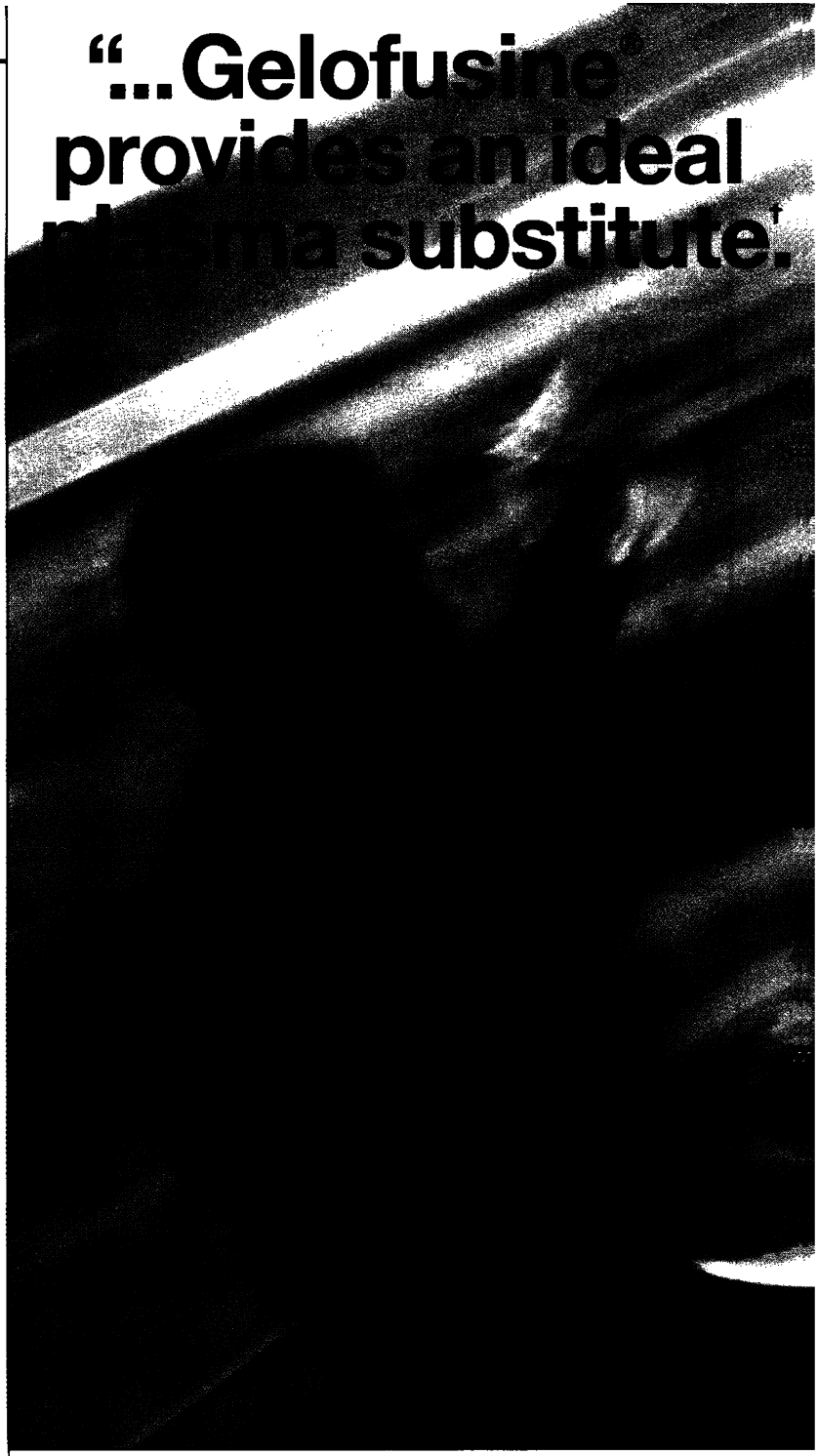
"...Gelofusine® provides an ideal plasma substitute.†



- 14% more gelatin content than polygeline.
- Negligible Ca/K – no risk of clotting/hyperkalaemia, no need to change/flush lines.
- Significantly lower side-effect potential.
- Prolonged retention time in circulation due to the spread-open cha structure, net negative charge and greater COP.
- Cost-effectiveness.

Now with *New* easy-access port

When action is needed fast, so is Gelofusine®, from B Braun because, when compared with urea-linked gelatin (polygeline), succinylated gelatin (Gelofusine®) is the informed choice. Further information is available on request.

ɹecify Gelofusine® from B Braun –
ɹe informed choice.

ebb, A.R. et.al. – Int. Care Med 1989; 15: 116-120.

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