USER INFORMATION
READ CAREFULLY

INFUSOL® SG
SUCCINYLATED GELATIN (Bovine) INTRAVENOUS INFUSION 4% w/v

Composition:

Succinylated Gelatine (Modified Fluid Gelatin)	40 g/L

Electrolytes (approx):	**mmol/L**	**(mEq/L)**
Sodium Ion (Na^+)	154	154
Chloride Ion (Cl^-)	120	120
Osmolarity:	274 mOsm/L	

Characteristic:
Succinylated Gelatin (Modified Fluid Gelatin) 4% w/v solution is clear and faintly yellow intravenous (IV) solution.

Pharmacodynamics:
INFUSOL® SG is a colloidal plasma substitute. When used in the treatment of hypovolaemia INFUSOL® SG produces significant increases in blood volume, cardiac output, stroke volume, blood pressure, urinary output and oxygen delivery. INFUSOL® SG promotes osmotic diuresis, thereby helping to protect the kidneys from the adverse effects of hypovolaemia.

Pharmacokinetics:
The half-life of INFUSOL® SG is about 4 hours, with the majority of the dose administered being eliminated by renal excretion within 24 hours.

Indications:
As colloidal volume substitute for:
- prophylaxis and treatment of absolute and relative hypovolaemia (e.g. following shock due to haemorrhage or trauma, peri-operative blood losses, burns, sepsis)
- prophylaxis of hypotension (e.g. in connection with induction of epidural or spinal anaesthesia)
- haemodilution
- extra-corporeal circulation (heart-lung machine, haemodialysis)

Recommended Dosage:
The volume and rate of infusion will depend on the condition of the patient. The rate of administration can be increased by the application of pressure to the container or by adjusting the giving set pump. When given rapidly INFUSOL® SG should be warmed to not more than 37°C if possible. In severe acute blood loss, INFUSOL® SG may be given rapidly (500mL in 5-10 minutes) until signs of hypovolaemia are relieved. When large volumes are given, suitable monitoring should be used 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, INFUSOL® SG may be used concomitantly with blood, the rate and amount of which depends on 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 INFUSOL® SG, it can be given through the same giving set since INFUSOL® SG has negligible calcium content and therefore does not clot blood. INFUSOL® SG can also be used to reconstitute packed red cells.

Route of Administration: I.V.

Contraindications:
INFUSOL® SG is contra-indicated in patients with a known hypersensitivity to succinylated gelatin.

Warning and Precautions:
Severe anaphylactic or anaphylactoid reactions have been reported following the intravenous administration of succinylated gelatin. These are rare, having an incidence of between 1 in 6,000 and 1 in 13,000 units.

However, they may be more likely to occur if INFUSOL® SG is given rapidly to normovolaemic patients, and may be assumed to be more hazardous in patients with known allergic conditions such as asthma.

Caution should be exercised in infusing INFUSOL® SG in any patient liable to develop circulatory overload (for example, congestive cardiac failure or renal failure with oliguria or anuria).

Due to possible cross-reactions involving the allergen galactose-alpha-1,3-galactose (alpha-Gal), the risk of sensitilization 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. In these patients, INFUSOL® SG should be administered only after a careful assessment of benefit/risk, including alternative treatments, and only under close supervision of well trained personnel with resuscitation equipment ready.

Interactions with other medicaments:
No interactions have been reported.

Incompatibilities:
INFUSOL® SG does not interfere with blood grouping or cross-matching.

Pregnancy and Lactation:
There are no adequate studies in pregnant and lactating women. As with all drugs, the benefits and the risks must be assessed.
INFUSOL® SG may be used in the initial treatment of blood loss during pregnancy where plasma volume replacement is needed.

Adverse Effects/Undesirable Effects:
Possible anaphylactic or anaphylactoid reaction, a list of rare adverse effects that have been associate with the admistration of succinylated gelatin is given below;
Rare effects (> 1 in 10,000 to < 1 in 1,000)
Immune system disorders: Anaphylactic or naphylactoid reaction.
Nervous system disorders: Tremor.
Cardiac disorders: Tachycardia.
Vascular disorders: Hypotension, hypertension.
Respiratory, thoracic and mediastinal disorders: Wheezing, dyspnoea, hypoxia.
Skin and subcutaneous tissue disorders: Urticarial reactions, sweating.
General disorders and administration site conditions: Chills, pyrexia.

Overdose and Treatment:
An overdose of INFUSOL® SG may give rise to circulatory overload and electrolyte imbalance. This potential is increased in patients with pre-existing cardiac or renal impairment. The use of INFUSOL® SG in such patients should be accompanied by careful attention to dosage and administration.

Storage Conditions:
Do not store above 30°C. Do not freeze or refrigerate.

Shelf Life:
2 years from manufacturing date. Do not use after expiry.

Dosage form and packaging available:
500mL x 20 LDPE plastic bottle per carton

Manufacturer/ Product Registration Holder:

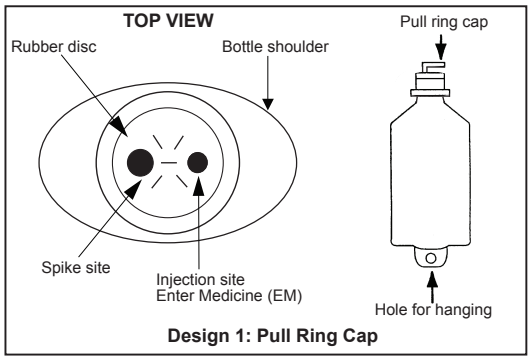
AIN MEDICARE SDN.BHD.
Lot 4933, 4934 & PT2464, Jalan 6/44, Kaw. Perindustrian Pengkalan Chepa 2, 16100 Kota Bharu, Kelantan, MALAYSIA.

HANDLING INSTRUCTION

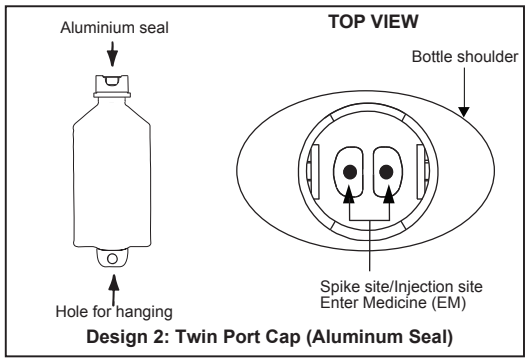
AIN MEDICARE INTRAVENOUS INFUSION FLUID IN LOW DENSITY POLYETHYLENE (LDPE) BOTTLE

The bottle is made from injectable grade polyethylene.

PARTS OF THE PLASTIC BOTTLE



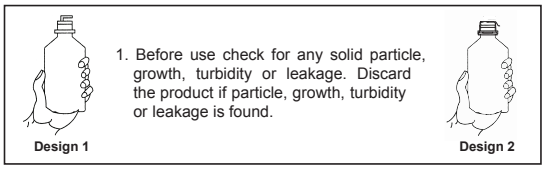
Design 1: Pull Ring Cap

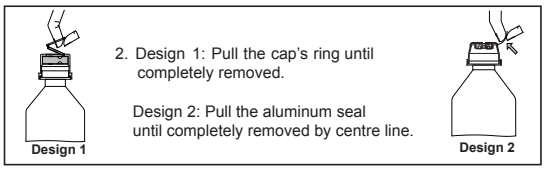


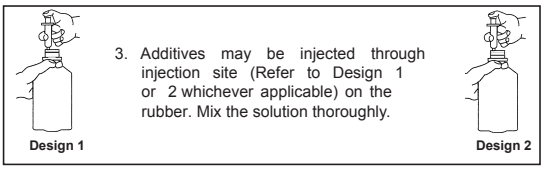
Design 2: Twin Port Cap (Aluminum Seal)

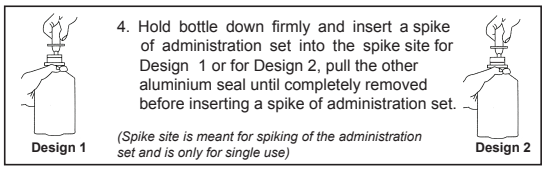
Top view after pull ring cap is removed. Please refer whichever applicable design.

INSTRUCTION FOR THE USAGE OF IV ADMINISTRATION SET & ADDITION OF DRUG









Date of Revision: 01/09/2019