

USER INFORMATION
READ CAREFULLY
INFUSOL® NS
SODIUM CHLORIDE 0.9% w/v INTRAVENOUS INFUSION BP

Composition:

Sodium Chloride BP 9 g/L

Electrolytes:	mmol/L	mEq/L
Sodium Ion (Na ⁺)	150	150
Chloride Ion (Cl ⁻)	150	150
Osmolarity :	308 mOsm/L	

INFUSOL® NS is an isotonic solution containing 150 mmol each of Sodium and Chloride per litre.

Product Description:

A clear and colourless solution.

Pharmacodynamics:

Sodium is the primary cation of the extracellular space and together with various anions, regulates the size of this. Sodium and Potassium are the major mediators of bioelectric processes within the body. The Sodium content and the liquid metabolism of the body are closely coupled to each other. Each deviation of the plasma sodium concentration from the physiological one simultaneously affects the fluid status of the body.

An increase in the Sodium content of the body also means reduction of the body's free water content independent of the serum osmolality. A 0.9 per cent Sodium Chloride solution has the same osmolality as plasma. Administration of this solution primarily leads to a replenishment of the interstitial space which is about 2/3 of the entire extracellular space. Only 1/3 of the administered volume remains in the intravascular space. Therefore, the haemodynamic effect of the solution is of short duration only.

Pharmacokinetics:

The total Sodium content of the body is ca. 80 mmol/kg of which ca. 97% is extracellular and ca. 3% intracellular. The daily turnover is ca. 100 - 180 mmol (corresponding to 1.5 - 2.5 mmol/kg body weight). The kidneys are the major regulator of the Sodium and water balances. In cooperation with the hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone) and the hypothetical natriuretic hormone they are primarily responsible for keeping the volume of the extracellular space constant and regulating its fluid composition. Chloride is exchanged for hydrogen carbonate in the tubule system and is thus, involved in the regulation of the acid base balance.

Indication:

- Plasma isotonic fluid replacement.
- Sodium and Chloride depletion.
- Hypochloremic alkalosis.
- Vehicle solution for supplementary medication.

Recommended Dosage:

The dose is adjusted according to the actual requirements of water and electrolytes:

Maximum daily dose: 40 mL/kg BW, corresponding to 6 mmol of sodium per kg BW.

Infusion rate: Up to 5 mL/kg BW/h, corresponding to 1.7 drops/kg BW/min.

Route of administration: Intravenous (IV)

Contraindications:

Hyperhydration, hypernatraemia, hypokalaemia, hypertension and acidotic situations.

Warnings and Precautions:

Warnings

INFUSOL® NS should only be administered with caution in cases of

- hypokalaemia
- hypernatraemia
- hyperchloraemia
- disorders where restriction of sodium intake is indicated, such as cardiac insufficiency, generalized oedema, pulmonary oedema, hypertension, eclampsia, severe renal insufficiency.

Precautions

- Clinical monitoring should include checks of the serum ionogram, the water balance, and the acid-base status.
- High infusion rates should be avoided in cases of hypertonic dehydration because of possible increases of plasma osmolality and plasma sodium concentration.
- In case of pressure infusion, which may be necessary in vital emergencies, all air must be removed from the container and the infusion set before the solution is administered.
- The compatibility of any additives to this solution should be checked before use. Single dose container. Discard all unused contents. Do not use if leakage is detected. If any visible solid particles, growth or turbidity appears during storage, the product should not be used.

Interactions with Other Medicaments:

When mixing with other medicaments, physical or chemical incompatibilities should be considered.

Pregnancy and Lactation:

INFUSOL® NS can be used as indicated. Physicians should carefully consider the potential risks and benefits for each specific patient before administering INFUSOL® NS.

Adverse Effects/Undesirable Effects:

Administration of larger amounts may lead to hypernatraemia and hyperchloraemia. When infused through a peripheral vein over a long time, thrombophlebitis can occur. Patients are advised to inform their doctor or pharmacist if they notice any adverse effect not mentioned in this leaflet.

Symptoms and Treatment of Overdose:

General adverse effects of excess sodium in the body include nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation and lachrymation, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, convulsions, coma and death.

An excessive volume of INFUSOL® NS may lead to hypernatraemia (which can lead to CNS manifestations, including seizures, coma, cerebral oedema and death) and Sodium overload (which can lead to central and/or peripheral oedema) and should be treated by an attending specialised physician.

Excess Chloride in the body may cause a loss of Bicarbonate with an acidifying effect.

When INFUSOL® NS is used as a diluent for injectable preparations of other drugs, the signs and symptoms of over infusion will be related to the nature of the additives being used. In the event of accidental over infusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant and supportive measures should be provided as necessary.

Incompatibilities:

As with all parenteral solutions compatibility of the additives with the solution must be assessed before addition. In the absence of compatibility studies, this solution must not be mixed with other medicinal products. Those additives known to be incompatible should not be used.

Shelf Life:

5 years from manufacturing date in proper storage condition in LDPE Ampoule.

5 years from manufacturing date in proper storage condition in LDPE Bottle.

3 years from manufacturing date in proper storage condition in PVC Medical Collapsible Bag.

Do not use after expiry.

Storage condition:

Do not store above 30°C.

Dosage form and packaging available:

- 5 mL x 20 LDPE plastic ampoule per Box
- 10 mL x 20 LDPE plastic ampoule per Box
- 20 mL x 20 LDPE plastic ampoule per Box
- 100 mL x 20 LDPE plastic bottle per Carton
- 250 mL x 20 LDPE plastic bottle per Carton
- 500 mL x 20 LDPE plastic bottle per Carton
- 500 mL x 10 LDPE plastic bottle per Carton
- 1000 mL x 10 LDPE plastic bottle per Carton
- 500 mL x 20 PVC Medical plastic collapsible bag per Carton
- 1000 mL x 10 PVC Medical plastic collapsible bag per Carton

Manufacturer / Product Registration Holder:

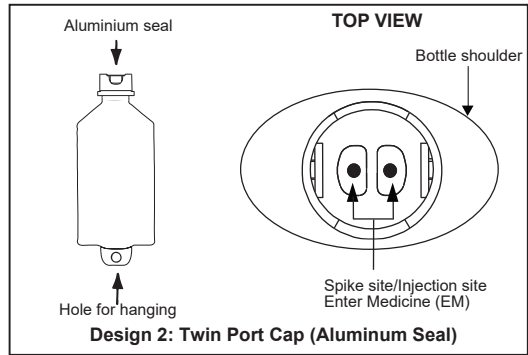
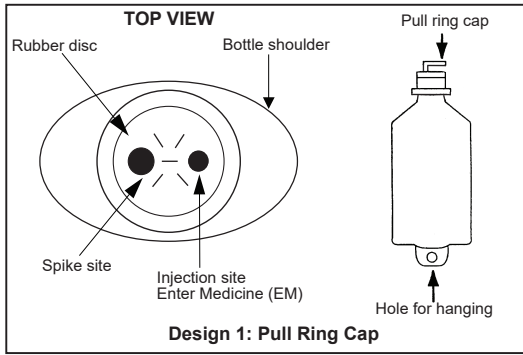
 **AIN MEDICARE®** Lot 4933, 4934 & PT2464, Jalan 6/44, Kaw. Perindustrian Pengkalan Chepa 2, 16100 Kota Bharu, Kelantan, MALAYSIA

HANDLING INSTRUCTION

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

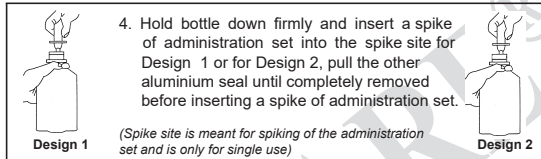
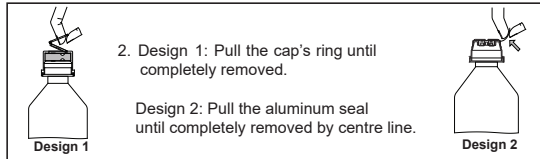
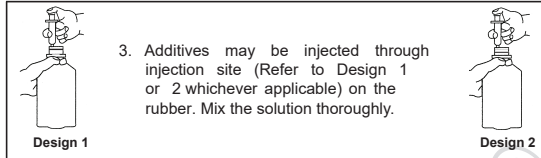
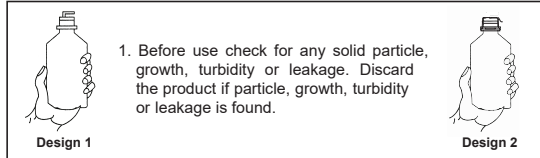
The bottle is made from injectable grade polyethylene.

PARTS OF THE PLASTIC BOTTLE



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

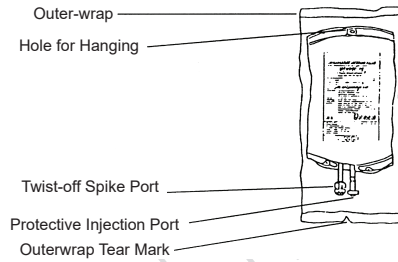
INSTRUCTION FOR THE USAGE OF IV ADMINISTRATION SET & ADDITION OF DRUG



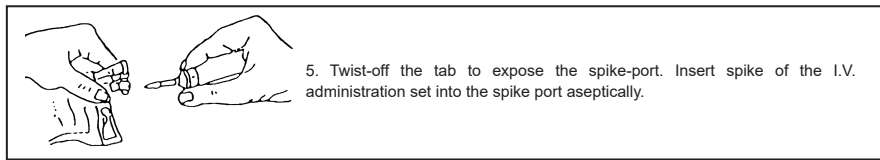
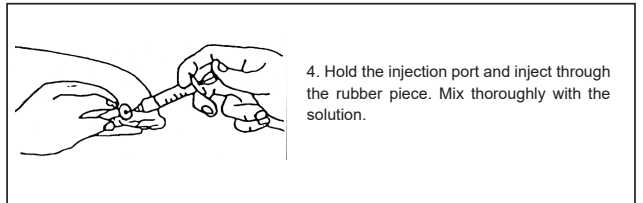
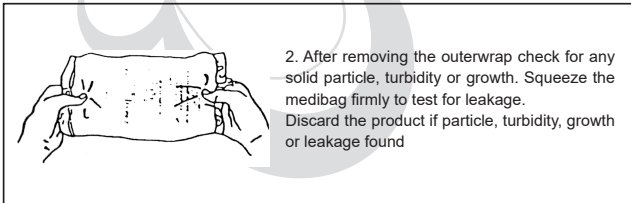
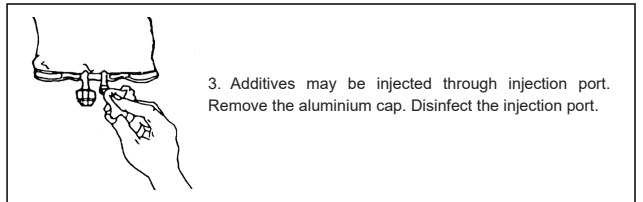
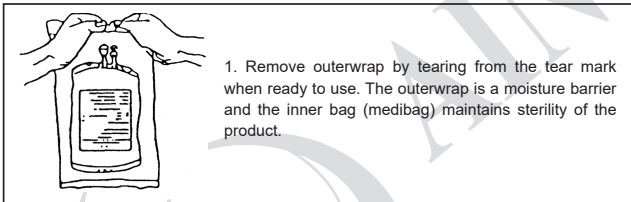
AIN MEDICARE INTRAVENOUS INFUSION FLUID IN PVC MEDICAL COLLAPSIBLE BAG

The Intravenous solution in medibag is packed and sterilized in an outerwrap.

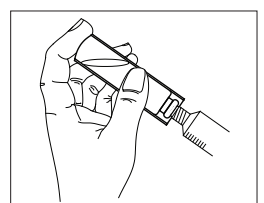
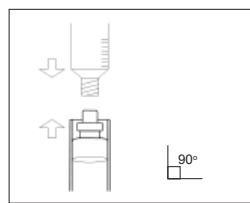
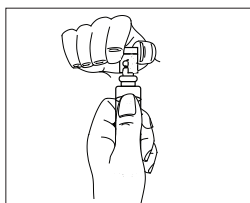
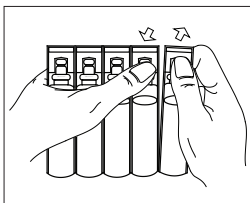
PARTS OF THE COLLAPSIBLE BAG



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



AIN MEDICARE INJECTION SOLUTION IN LOW DENSITY POLYETHYLENE (LDPE) AMPOULE



1. Detach ampoule along parting line

2. Twist off tab

3. Attach luer lock syringe, luer slip syringe or hypodermic needle vertically to the ampoule.

4. Draw out injection fluid using luer lock syringe, luer slip syringe or hypodermic needle. Ensure the connection is tightly secured for effective aspiration of the liquid.