USER INFORMATION
READ CAREFULLY

INFUSOL® HSD10

SODIUM CHLORIDE 0.45% w/v & DEXTROSE 10% w/v INTRAVENOUS INFUSION BP

Composition:

Sodium Chloride BP	4.5 g/L
Dextrose Anhydrous BP	100.0 g/L

Electrolytes (approx):	**mmol/L**	**mEq/L**
Sodium Ion (Na^+)	77	77
Chloride Ion (Cl^-)	77	77
Osmolarity :	709 mOsm/L	
Caloric Value: Approx.	1675 kJ/L = 400 kcal/L	

Product Description:
A colourless or faintly strawed coloured solution. Hypertonic intravenous solution supplies physiologically free water.

Pharmacodynamic:
10% Glucose with half Saline supplies energy, along with correction of electrolyte imbalance. It is also supplies water along with essential salts. This is because Sodium Chloride is distributed easily and builds up the salt level rapidly. Thus the second and third step of the dehydration therapy is achieved. This combination of Sodium Chloride with Glucose eliminates the problem of incompatibility which occurs when plain Glucose is administered with preserved blood. This results in aggregation of erythrocytes which may lead to transfusion problems.

Pharmacokinetics:
Sodium Chloride is readily absorbed in the body. It is present in all types of body fluids but primarily in extracellular fluid. The osmotic equilibrium is maintained by excretion in urine.
Glucose is rapidly absorbed from the gastrointestinal tract. It is metabolised to carbon dioxide and water with the release of 3.4 calories/gram of energy. It is readily metabolised. It may deaccelerate body protein and nitrogen losses, promote glycogen deposition and decrease/prevent ketosis in sufficient dose.
Bioavailability : As the solution is directly administered into the blood, it is 100% available.

Indication:
Dehydration, Sodium and Chloride depletion, hyperchloremic alkalosis, energy supply (parenteral nutrition), vehicle solution for supplementary medication.

Recommended Dosage:
Dose varies depending on the clinical condition and size of the patient.
Approximately 1000mL/day in average adult.
Drop rate: Up to 120 drops/min corresponding to 360 mL/h.

Route of administration: Intravenous (IV)

Contraindications:
Hyperhydration, Oedema, Hypertension, Hypernatraemia, Diabetes mellitus, Hypotonic dehydration, Acidosis situations.

Warning and Precautions:
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.

Statement on usage during pregnancy and lactation:
As advised by the physician.

Adverse Effects/Undesirable Effects:
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.
Excessive administration of sodium chloride causes hypernatraemia, the most serious effect of which is dehydration of internal organs, especially the brain. Excess chloride in the body may cause a loss of bicarbonate with an acidifying effect.
Reactions due to solution or technique of administration: Febrile response; local tenderness; abscess; tissue necrosis or infection at injection site; venous thrombosis or phlebitis extending form injection site; extravasation; hypervolemia.
If an adverse reaction occurs, discontinue the infusion, evaluate the patient, institute appropriate countermeasures and save the remainder of the fluid for examination.

Overdose and Treatment:
Hypernatraemia requires the use of sodium – free fluids and the cessation of excessive sodium intake. Very occasionally dialysis has been needed in severe hypernatraemia.
Iso-osmotic overload is managed by sodium and water restriction plus measures to increase renal sodium and water loss such as 'loop diuretics' (eg. Frusemide) or, in specific circumstances, antimineralocorticoid agents.

Shelf Life:
5 years from manufacturing date in the proposed storage condition for LDPE Bottle.
3 years from manufacturing date in the proposed storage condition for PVC Medical Collapsible Bag.
Do not use after expiry.

Storage Condition:
Do not store above 30°C.

Dosage form and packaging available:
500mL x 20 LDPE plastic bottle per carton
500mL x 20 PVC Medical plastic collapsible bag per carton

Manufacturer / Product Registration Holder:

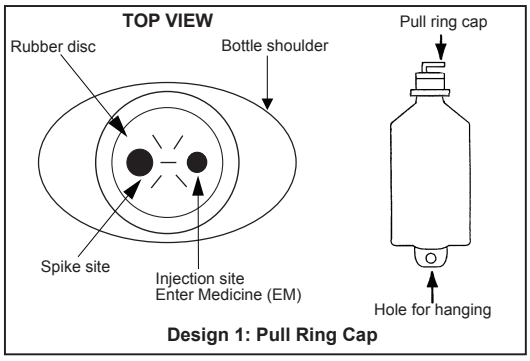
AIN MEDICARE SDN.BHD.
Lot 4933, 4934 & PT2464, Jalan 6/44, Kaw. Perindustrian Pengkalan Chepa 2, 16100 Kota Bharu, Kelantan, MALAYSIA.

HANDLING INSTRUCTION

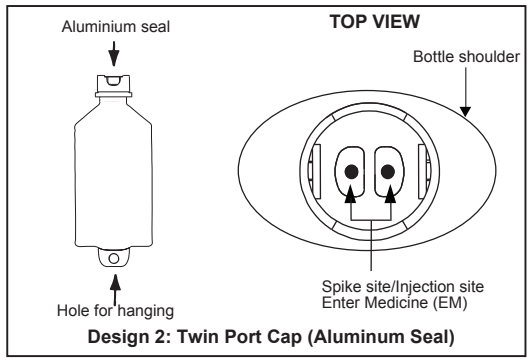
AIN MEDICARE INTRAVENOUS INFUSION FLUID IN LOW DENSITY POLYETHYLENE (LDPE) BOTTLE

The bottle is made from injectable grade polyethylene.

PARTS OF THE PLASTIC BOTTLE



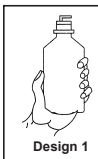
Design 1: Pull Ring Cap



Design 2: Twin Port Cap (Aluminum Seal)

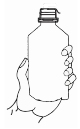
Top view after pull ring cap is removed. Please refer whichever applicable design.

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

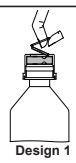


Design 1

1. Before use check for any solid particle, growth, turbidity or leakage. Discard the product if particle, growth, turbidity or leakage is found.



Design 2

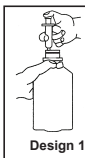


Design 1

2. Design 1: Pull the cap's ring until completely removed.

Design 2: Pull the aluminum seal until completely removed by centre line.

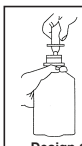
Design 2



Design 1

3. Additives may be injected through injection site (Refer to Design 1 or 2 whichever applicable) on the rubber. Mix the solution thoroughly.

Design 2



Design 1

4. Hold bottle down firmly and insert a spike of administration set into the spike site for Design 1 or for Design 2, pull the other aluminium seal until completely removed before inserting a spike of administration set.

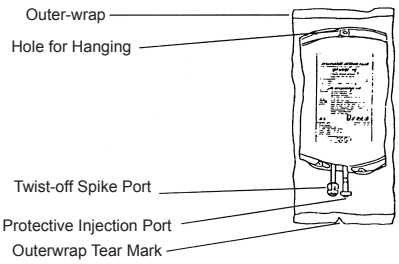
(Spike site is meant for spiking of the administration set and is only for single use)

Design 2

AIN MEDICARE INTRAVENOUS INFUSION FLUID IN PVC MEDICAL COLLAPSIBLE BAG

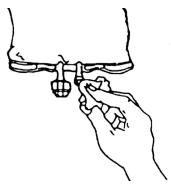
The Intravenous solution in medibag is packed and sterillized in an outerwrap.

PARTS OF THE COLLAPSIBLE BAG

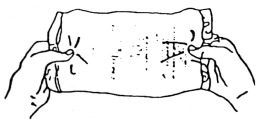


INSTRUCTION FOR THE USAGE OF IV ADMINISTRATION SET & ADDITION OF DRUG

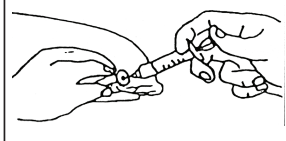
1. Remove outerwrap by tearing from the tear mark when ready to use. The outerwrap is a moisture barrier and the inner bag (medibag) maintains sterility of the product.



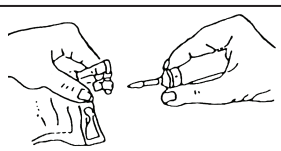
3. Additives may be injected through injection port. Remove the aluminium cap. Disinfect the injection port.



2. After removing the outerwrap check for any solid particle, turbidity or growth. Squeeze the medibag firmly to test for leakage.
Discard the product if particle, turbidity, growth or leakage found



4. Hold the injection port and inject through the rubber piece. Mix thoroughly with the solution.



5. Twist-off the tab to expose the spike-port. Insert spike of the I.V. administration set into the spike port aseptically.

Date of Revision: 01/05/2020