USER INFORMATION
READ CAREFULLY

INFUSOL® D20
DEXTROSE 20% w/v INTRAVENOUS INFUSION BP

Composition:
The solution contains
Dextrose Anhydrous BP 200 g/L
Osmolarity : 1110 mOsm/L
Caloric Value : Approx. 3350 kJ/L = 800 kcal/L

Product Description:
The solution is a colourless or faintly strawed colour solution.

Pharmacodynamic:
Glucose provides energy.
Glucose when given intravenously with water metabolises into glycogen leaving water to be absorbed to correct fluid imbalance.
Glucose increases the movements of electrolytes across the semi-permeable membrane.

Pharmacokinetics:
Glucose is rapidly absorbed from the gastrointestinal tract. It is metabolised to carbon dioxide and water with the release of approx. 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. As the product is administered through intravenous route it is 100 % bioavailable.

Indication:
Parenteral nutrition
Hypoglycemia
High caloric carbohydrate therapy, especially when fluid intake is limited.

Recommended Dosage:
Adult patients
According to individual requirements:
Dextrose 20% : up to 30mL/kg of body weight per day.
Drop rate (for patients with approximately 70kg of body weight)
Dextrose 20% : up to 40 drops/min or 120mL/h.

Pediatric patients
Mean requirements/kg of body weight and per day.
1^{st} year of life : 8 - 15g dextrose.
2^{nd} year of life : 12 - 15g dextrose.
3^{rd} - 5^{th} year of life : 12g dextrose.
6^{th} - 10^{th} year of life : 10g dextrose.

Route of administration: Intravenous (IV)
Glucose solutions with a concentration greater than 5% are hypertonic and should be administered by slow intravenous infusion via a central vein.

Contraindications:
Diabetes mellitus (with the exception of hypoglycaemic conditions).
Glucose intolerance, hypotonic dehydration if lacking electrolytes are not replaced.
Over hydration.
Hypokalemia.
Hyperosmolar coma.
Acidosis.

Warnings and Precautions:
Blood glucose, serum electrolytes and water balance should be monitored regularly. Electrolytes are to be supplemented as required. The compatibility of any additives to this solution should be checked before use. Dextrose solutions should not be administered through the same infusion set through which also blood has or may be given because of the risk of pseudoagglutination.
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.

Adverse Effects/Undesirable Effects:
Dextrose Injection and particularly hypertonic Dextrose Injection may have low pH, and such solution when injected may irritate the venous intima near the site of the injection to cause thrombophlebitis. Hyperglycaemia and renal losses may occur in case of reduced glucose tolerance. These manifestations are normally prevented by reducing the dosage and/or giving insulin. Enhanced bilirubin and lactate levels may be found if the recommended dosage is exceeded.

Overdose and Treatment:
Dextrose solutions I.V can cause fluid overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary oedema. Hyperglycemia and glucosuria may be functions of rate of administration or metabolic insufficiency. To minimise these conditions, slow infusion rate, monitor blood and urine glucose; if necessary, stop administration of dextrose or/and administer insulin.

Storage condition: Do not store above 30°C.

Shelf Life:
3 years from manufacturing date in the proposed storage condition.
Do not use after expiry.

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:

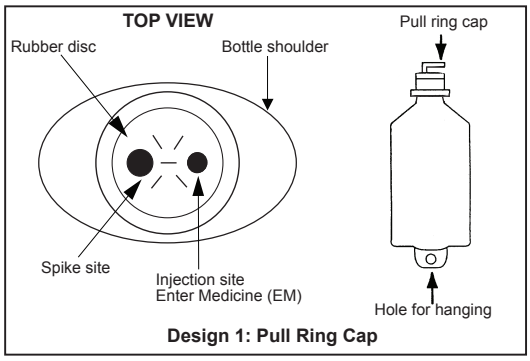
AIN MEDICARE SDN.BHD.
Lot 4933, 4934 & PT2464, Jalan 6/44, Kaw. Perindustrian Pengkalan Chepa 2, 16100 Kota Bharu, Kelantan, MALAYSIA.

HANDLING INSTRUCTION

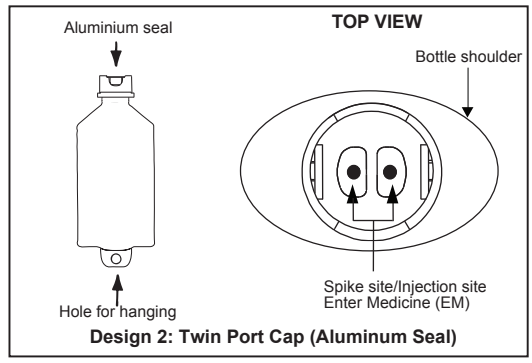
AIN MEDICARE INTRAVENOUS INFUSION FLUID IN LOW DENSITY POLYETHYLENE (LDPE) BOTTLE

The bottle is made from injectable grade polyethylene.

PARTS OF THE PLASTIC BOTTLE



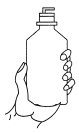
Design 1: Pull Ring Cap



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.

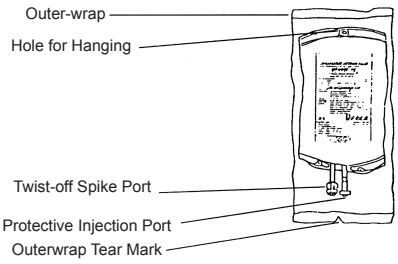
(Spike site is meant for spiking of the administration set and is only for single use)

Design 2

AIN MEDICARE INTRAVENOUS INFUSION FLUID IN PVC MEDICAL COLLAPSIBLE BAG

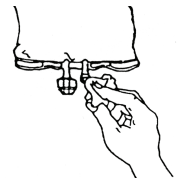
The Intravenous solution in medibag is packed and sterillized in an outerwrap.

PARTS OF THE COLLAPSIBLE BAG

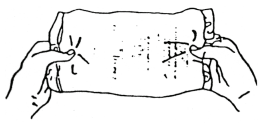


INSTRUCTION FOR THE USAGE OF IV ADMINISTRATION SET & ADDITION OF DRUG

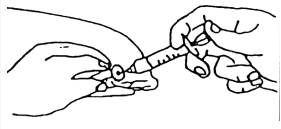
1. Remove outerwrap by tearing from the tear mark when ready to use. The outerwrap is a moisture barrier and the inner bag (medibag) maintains sterility of the product.



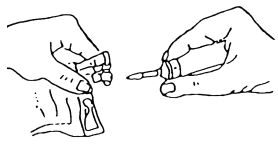
3. Additives may be injected through injection port. Remove the aluminium cap. Disinfect the injection port.



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: 01/11/2019