USER INFORMATION
READ CAREFULLY

INFUSOL® NSD5
SODIUM CHLORIDE 0.9% w/v & DEXTROSE 5% w/v INTRAVENOUS INFUSION BP

Composition:

Sodium Chloride BP	9 g/L
Dextrose Anhydrous BP	50 g/L

Electrolytes (approx) :	**mmol/L**	**mEq/L**
Sodium Ion (Na^+)	150	150
Chloride Ion (Cl^-)	150	150
Osmolarity :	585 mOsm/L	
Caloric Value : Approx.	837 kJ/L = 200 kcal/L	

Product Description:
A colourless or faintly straw-coloured solution. Hypertonic IV solution providing 150mmol/L Sodium and 50g/L of Dextrose.

Pharmacodynamic:
5% Glucose with Normal 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.
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 results in a reduction of the body's free water content independent of the serum osmolality. Glucose is metabolised ubiquitously as the natural substrate of the cells of the body. Under physiological conditions Glucose is the most important energy-supplying carbohydrate with a caloric value of ca. 16 kJ or 3.75 kcal/g. Nervous tissue, erythrocytes and medulla of the kidneys are amongst the tissues with an obligate requirement for Glucose. In adults, the concentration of Glucose in the blood is 70 – 100 mg/100 mL, or 3.9 – 5.6 mmol/L (fasting).
Glucose serves for the synthesis of glycogen as the storage form of carbohydrates and it is subject to glycolysis to pyruvate and lactate for energy production in the cells. Glucose also serves to maintain the blood sugar level and for the synthesis of important body components. It is primarily insulin, glucagon, glucocorticoids and catecholamines that are involved in the regulation of the blood sugar concentration.
A normal electrolyte and acid-base status is a prerequisite for the optimal utilisation of administered glucose. So, an acidosis in particular can indicate impairment of the oxidative glucose metabolism.

Pharmacokinetics:
Absorption
As the solution is administered by intravenous infusion the bioavailability of the solution is 100%.

Distribution
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). On infusion Glucose is first distributed in the intravascular space and then is taken up into the intracellular space. The total body Chloride in adults is about 33 mmol/kg body weight. Serum Chloride is maintained at 98 - 108 mmol/L.

Biotransformation
The kidneys are the major regulator of the Sodium and Water balances. In co-operation with the hormonal control mechanisms (renin-angiotensinaldosterone 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.
In glycolysis glucose is metabolised to pyruvate or to lactate. Lactate can be partially re-introduced into the Glucose metabolism (Cori cycle). Under aerobic conditions pyruvate is completely oxidized to Carbon Dioxide and Water. Glucose utilisation disturbances (Glucose intolerance) can occur under conditions of pathological metabolism. These mainly include diabetes mellitus and states of metabolic stress (e.g., intra-, and postoperatively, severe disease, injury), hormonally mediated depression of Glucose tolerance, which can even lead to hyperglycaemia without exogenous supply of the substrate. Hyperglycaemia can - depending on its severity - lead to osmotically mediated renal fluid losses with consecutive hypertonic dehydration, to hyperosmotic disorders up to and including hyperosmotic coma.
Metabolism of glucose and electrolytes are closely related to each other. Insulin facilitates potassium influx into cells. Phosphate and Magnesium are involved in the enzymatic reactions associated with Glucose utilization. Potassium, Phosphate and Magnesium requirements may therefore increase following Glucose administration and may therefore have to be monitored and supplemented according to individual needs. Especially cardiac and neurological functions may be impaired without supplementation.

Elimination
Sodium and Chloride are excreted via sweat, urine and the gastrointestinal tract. Chloride is exchanged for Hydrogen Carbonate in the tubule system and is, thus, involved in the regulation of the acid base balance. The final products of the complete oxidation of Glucose are eliminated via the lungs (Carbon Dioxide) and the kidneys (water). Practically no Glucose is excreted renally by healthy persons. In pathological metabolic conditions (e.g., diabetes mellitus, post-aggression metabolism) associated with hyperglycaemia (blood glucose concentrations of more than 120 mg/100 ml or 6.7 mmol/l), Glucose is also excreted via the kidneys (glucosuria) when the maximum tubular resorption capacity (180 mg/100 ml or 10 mmol/l) is exceeded.

Indication:
- Dehydration
- Sodium and Chloride depletion
- Caloric supply
- Vehicle solution for supplementary medication

Recommended Dosage:
Dose varies depending on the clinical condition and size of the patient.
Approximately 1000mL/day in average adults.
Drop Rate: 120 - 180 drops/min corresponding to 360 - 540 mL/h.

Route of administration: Intravenous (IV)

Contraindications:
Hyperhydration, Oedema. Hypertension, Hypernatraemia, Hypokalaemia, Diabetes mellitus.

Warning and Precautions:
INFUSOL® NSD5 should only be administered with caution in cases of;
- Hypernatraemia
- Hyperchloraemia
- Disorders where restriction of fluid or sodium intake are indicated, such as cardiac insufficiency, generalized oedema, hypertension, pre-eclampsia, severe renal insufficiency.
- In patients with acute ischaemic stroke and hyperglycaemia the glucose level should be corrected before application of this solution.
- Hypokalaemia

To prevent development of the osmotic demyelination syndrome the increase of the serum Sodium level should not exceed 9 mmol/L/day. As a general recommendation a correction rate of 4 to 6 mmol/L/day is reasonable in most cases, depending on patient condition and concomitant risk factors.
Clinical monitoring should include checks of the serum electrolytes (especially Potassium), Glucose level, the acid-base and water balance.
In post-operative and post-traumatic conditions and in conditions of impaired Glucose tolerance: only administer with monitoring of blood glucose level. The solution should not be administered through the same infusion equipment simultaneously, before or after an administration of blood because of the possibility of pseudo-agglutination.
Paediatric population
Premature or term infants may retain an excess of Sodium due to immature renal function. In premature or term infants, repeated infusion of Sodium Chloride should therefore only be given after determination of the serum Sodium level. In addition, intravenous fluid therapy should be closely monitored in the paediatric population as they may have impaired ability to regulate fluids and electrolytes. Adequate hydration and urine flow must be ensured and fluid balance, plasma and urinary electrolyte concentrations should be closely monitored.

Cautions:
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:
Medicinal products causing sodium retention
The concomitant use of sodium-retaining drugs (e.g., corticosteroids, nonsteroidal anti-inflammatory agents) may lead to oedema.

Medicinal products influencing the glucose metabolism
Interactions with medicinal products influencing the glucose metabolism e.g., corticosteroids should be considered.

Pregnancy and Lactation:
Pregnancy
There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of INFUSOL® NSD5 in pregnant women. Caution should be exercised when prescribing to pregnant women, especially in the presence of pre-eclampsia. Careful monitoring of blood glucose is necessary.

Breast-feeding
As all active ingredients are present in human body, no negative effects are anticipated if used during lactation. Therefore, the solution can be used during breast-feeding.

Side 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.
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.

Symptoms and Treatment of Overdose:
Symptoms
Overdose of INFUSOL® NSD5 may result in hyperhydration, with increased skin tension, venous congestion and development of oedema. Dilution of serum electrolytes, electrolyte imbalances, notably hypernatraemia, hyperchloraemia and hypokalae-mia, acid-base imbalances may occur. In addition, hyperglycaemia, glucosuria and hyperosmolar dehydration and, in extreme cases, hyperglycaemic-hyperosmolar coma may occur.

Treatment
Dependent on the severity of the disorders immediate stop of infusion, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances, administration of insulin if necessary. In severe cases of overdose or in cases of oligo or anuria dialysis may be necessary.

Incompatibilities:
When mixing with other medicinal products possible incompatibilities should be considered. It should be remembered that the solution has an acidic pH, which can cause precipitation in the mixture.

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

Storage Condition:
Do not store above 30°C.

Dosage form and packaging available:
500mL x 10 LDPE plastic bottle per carton
500mL x 20 LDPE plastic bottle per carton
1000mL x 10 LDPE plastic bottle per carton

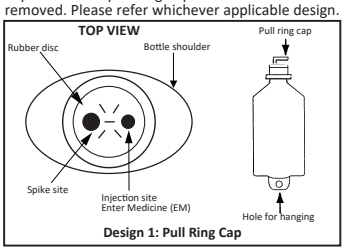
Manufacturer / Product Registration Holder:

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

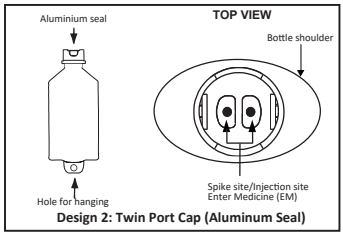
HANDLING INSTRUCTION

AIN MEDICARE INTRAVENOUS INFUSION FLUID IN LOW DENSITY POLYETHYLENE (LDPE) BOTTLE
The bottle is made from injectable grade polyethylene.
PARTS OF THE PLASTIC BOTTLE

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

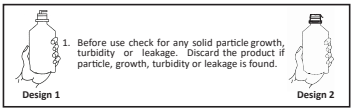


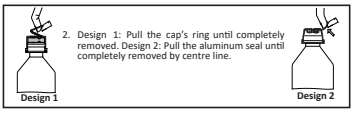
Design 1: Pull Ring Cap

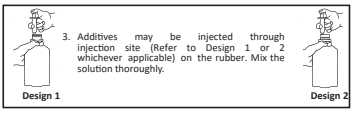


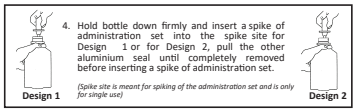
Design 2: Twin Port Cap (Aluminum Seal)

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









Date of Revision: 01.07.2023