DANA PHARMACEUTICALS LIMITED, IBADAN.

| Module 1 | ADMINISTRATIVE INFORMATION |
|---|---|
| 1.3 | Product Information |
| 1.3.1 | Summary Product Characteristics (SPC) |

**Summary Product Characteristics (SPC)**

**1. Name of the medicinal product**

**1.1 (Invented) name of the medicinal product**

**DARROWS SOLUTION HALF STRENGTH INTRAVENOUS INFUSION BP**

**1.2 Strength**

| | |
|---|---|
| Sodium Chloride | 1.00gm |
| Sodium Lactate | 1.475 gm |
| Potassium Chloride | 0.65 gm |

**1.3 Pharmaceutical form**

Infusion.

**2. Qualitative and quantitative composition**

Each 100 ml contains:

| | |
|---|---|
| Sodium Chloride | 1.00gm |
| Sodium Lactate | 1.475 gm |
| Potassium Chloride | 0.65 gm |
| Water for Injection | Qs to 100 ml |

**3. Pharmaceutical form**

Intravenous Infusion

**4. Clinical particulars**

**4.1 Therapeutic indications**

Sodium chloride is used in the management of deficiencies of sodium and chloride ions in salt-losing conditions. Sodium chloride solutions are used as a source of sodium chloride and water for hydration. The concentration and dosage of sodium chloride solutions for intravenous use is determined by several factors including the age, weight and clinical condition of the patient and in particular the patient's hydration state. Serum-electrolyte concentrations should be carefully monitored.

**4.2 SIDE EFFECTS**

Excessive administration of bicarbonate or other compound that are metabolized to form the bicarbonate anion may lead to hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms may include mood changes, tiredness, shortness of breath, muscle weakness and irregular heartbeat. Muscle hypertonicity, twitching, and tetany may develop especially in hypocalcaemic patients. Treatment of metabolic alkalosis associated with bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte balance. Replacement of calcium, chloride, and potassium ions may be of particular importance.

**4.3CONTRA-INDICATIONS**

Sodium chloride is contra-indicated in patients having acidosis, hypertonic dehydation, hypernatraemia and hyperkalemia.

Product containing potassium salts should be administered with considerable care to patients with cardiac disease or conditions predisposing to hyperkalemia, such as renal or adrenocoitical insufficiency, acute dehydration, or extensive tissue destruction as in severe burns.

It is general recommended that agents which can form the bicarbonate anion after metabolism should not be administered to patients with metabolic or respiratory alkalosis, hypocalcemia, or hypochlorhydia. Alkalinizing of urine by bicarbonate or bicarbonate precursors leads to increased renal clearance of acidic drugs such as salicylates and barbiturates. Conversely, urinary alkalinization prolongs the half-life of basic drugs and may lead to sodium over-loading and hyper-osmolality.

It should be given cautiously in digitilized patient.

The product should be administered with caution in patients with hypertension, heart failure, peripheral and pulmonary edema, impaired renal function, pre-eclampsia or other conditions associated with sodium retention.

Plasma electrolytes concentrations should be monitored during use.

**4.4 ADVERSE REACTIONS**

Cardiac toxicity is particular concern after intravenous administration. Pains and phlebitis may occur during intravenous administration of via the peripheral route.

Adverse effects of sodium chloride are attributable to electrolytes imbalance from excess sodium. There may also be effects due to specific anion. Retention of excess sodium ion in the body usually occurs when there is defective renal sodium excretion. This leads to accumulation of extra-cellular fluid to maintain normal plasma osmolality, which may result in pulmonary and peripheral oedema and their consequent effects. Hypernatraemia may occur after inappropriate intravenous administration of hypertonic

saline solution. The most serious effects of hypernatraemia is dehydration of the brain which causes somnolence and confusion progressing to convulsion, coma respiratory failure and death. Other symptoms include thirsty, reduced salivation and lachrymation, fever, tachycardia. Hypertension, headache, dizziness, restlessness, irritability and weakness.

Sodium salts should be administered with caution to patients with hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function, pre-eclampsia, or other conditions associated with sodium retention.

Parenteral potassium products should be used with caution in patients receiving drugs that increase serum potassium concentrated as with ACE inhibitors, cyclosporin and drugs that contain potassium.

Excessive administration of potassium may lead to hyperkalemia especially in patients with renal impairment. Symptoms include paraesthesia of extramities, muscle weakness, cardiac arrythmias**,** heart block, cardiac paralysis and mental confusion. Cardiac toxicity is of particular concern after intravenous administration of potassium.

## *4.5 ANTIDOTE IN THE EVENT OF OVER DOSAGE*

Treatment of the bicarbonate overdose consist of mainly of appropriate correction of fluid and electrolyte balance. Replacement of calcium, potassium and chloride ion may be of particular importance.

Calcium is administered to counteract the negative effect of hyperkalemia on cardiac excitability. Agents like insulin or sodium bicarbonate are used to promote the intracellular fluid compartment, and enhanced potassium excretion with exchange resins or dialysis.

### 4.6 TERATOGENICITY

Pregnancy to be restored before infusion.

### 5.0 Incompatibilities

Do not use equipment containing aluminum (e.g., needles, cannulae) that would come in contact with the drug solution as precipitates may form.

### 5.1 Shelf life

3 Years

### 5.2 Special precautions for storage

Store below 30 degree celcius.

**5.3 Nature and contents of container**

Flexible Poly vinyl chloride pouches filled with intravenous infusion and stoppered and overwrapped with low density polyethylene nylon material, the pouch size is 500 ml & 1000 ml packed inside a 5 ply corrugated cartons.

**5.4 Special precautions for disposal**

Use only if the solution is clear, without visible particles and if the Pouch is undamaged.
The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.
Using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of Pyrogens. In the case of adverse reaction, infusion must be stopped immediately.
Additives:
The product should be used immediately after opening. Discard after single use.
Discard any unused portion.
Do not reconnect partially used bags.
1. Opening
a. Remove the Pouch from the overwrapped nylons just before use.
b. Check for minute leaks by squeezing firmly. If leaks are found, discard solution, as sterility may be impaired.
c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.
2. Preparation for administration
3. Use an aseptic method to set up the infusion

**6. Registrant**

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