อ้างอิง ใบดำเนินการจัดทำวัสดุบรรจุหีบห่อใหม่หรือแก้ไขวัสดุบรรจุหีบห่อเดิม เลขที่ 023/63			ตรวจครั้งที่	1
ชื่อแบบ	เอกสารกำกับยา A.N.B. Iso. Sodium Chloride Inj (Malaysia)		กระดาษ	
พิมพ์ (สี)	1 สี (ดำ)		ขนาด	95x130 mm
หมายเหตุ			รหัสวัสดุ	001544-D02
ผู้จัดทำ	สุนันทา กุลไพศาล	ผู้ตรวจแบบ (Approved by)	4. จัดซื้อ ..... วันที่ ...../...../.....	
วันที่จัดทำ	27/02/63	1. การตลาด ..... วันที่ ...../...../.....	5. ผลิต ..... วันที่ ...../...../.....	
หน้า	1/1	2. ต่างประเทศ ..... วันที่ ...../...../.....	6. QC ..... วันที่ ...../...../.....	
		3. ทะเบียน ..... วันที่ ...../...../.....	7. QA ..... วันที่ ...../...../.....	

A.N.B. Iso. Sodium Chloride Inj

Controlled Medicine/*Ubat Terkawal*

Each 100 mL contains:

Sodium Chloride	0.9 g
Sterile Water for Injection	q.s. to 100 mL

Product Description: Sterile, clear, colourless solution

Pharmacodynamics/Pharmacokinetics: Solution of Isotonic Sodium Chloride is iso-osmotic with blood and is the strength often employed for fluid depletion; it is administered via a peripheral vein.

Indication: Fluid and electrolytes replenisher

Recommended Dosage: Intravenous infusion or as physician's order

Contraindications: Sodium chloride is contraindicated in patients with conditions in which administration of sodium chloride is detrimental.

Warnings:

1. It should be used with caution in patients with impaired renal or liver function, hypoproteinemia, hypertension, congestive heart failure or other edematous or sodium-retention states, or in those receiving corticosteroids.
2. It may cause hypernatremia associated with edema. Hyperosmotic solutions are irritant to the gastro-intestinal mucosa and may cause nausea, vomiting and diarrhea.

Precautions: Change in fluid balance, electrolyte concentrations and acid-base balance should be evaluated clinically and via periodic laboratory determinations during prolonged therapy with sodium chloride and in patients whose condition warrants such evaluation. Substantial changes may require additional electrolyte supplements or other appropriate therapy. Additional electrolyte supplementation may also be required in patients with substantial electrolyte losses resulting from conditions such as protracted nasogastric suctioning, vomiting, diarrhea, or GI fistula drainage. Sodium chloride should be used with extreme caution, if at all, in patients with congestive heart failure or other edematous or sodium-retaining conditions, in patients receiving corticosteroids or corticotrophin; particular caution is necessary in geriatric or postoperative patients. IV administration of sodium chloride may cause fluid and/or solute overload resulting in dilution of serum electrolytes, overhydration, congestive conditions, or pulmonary edema. The risk of dilutional conditions is inversely proportional to the electrolyte concentration administered, and the risk of solute overload and resultant congestive conditions with peripheral and/or pulmonary edema is directly proportional to the electrolyte concentration administered. Excessive IV administration of sodium chloride may result in hypokalemia.

Drug Interactions: Cautiously administer parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotrophin.

Adverse Effects: Reactions that may occur because of the solution (e.g. contamination) or administration technique include fever, infection at the site of injection, venous thrombosis or phlebitis extending from the site of

injection, and extravasation. Hypervolemia or symptoms resulting from an excess or deficit of one or more ion present in the solution may also occur. Excessive administration of sodium chloride may result in hypernatremia and large amounts of chloride may cause a loss of bicarbonate with an acidifying effect. If an adverse effect occurs during administration of sodium chloride injection, the infusion should be discontinued, the patient evaluated, appropriate therapeutic measures instituted if necessary, and the remainder of the fluid saves for examination if necessary.

Overdose:

(a) Brief clinical description symptoms

Overdose may cause pulmonary edema, generalized edema, headache, tinnitus, sensation of warmth in lips, tongue and torso, hypernatremia (characterized by abdominal, back and pelvic pain, diarrhea, muscle twitching, hyperreactivity, confusion, numbness stupor, convulsions or coma) and, occasionally, cellular dehydration. It must be used cautiously in patients with cardiac or renal impairment or hypoproteinemia.

(b) Treatment of Overdose

Hypernatremia itself is corrected with water by mouth or by intravenous infusion of 5% dextrose in water. Calculation of water requirements must be based on total body water, since water deficits are drawn from both intracellular and extracellular fluid and both must be repleted. For example, suppose a 70-kg man has a plasma sodium of 160mmol/L which is to be lowered to 140. Total body water is estimated as 60 percent of 70 kg, which is 42 L. To reduce plasma sodium, this volume must be increased to (160/140) x 42 L, which equals 48 L. Thus a positive water balance of 6 L (48–42) is required. Hypernatremia should be corrected slowly; no more than half the water deficit should be replaced in the first 12 to 24 h. As stated above, rapid correction of hypertonicity may cause central nervous function to deteriorate.

Storage Conditions: Store below 30°C. Keep out of reach of children. Discard unused portion.

Packaging:

- Polypropylene bottle of 50 x 100 mL
- Polypropylene bottle of 20 x 500 mL
- Polypropylene bottle of 10 x 1000 mL

Manufacturer:
A.N.B. Laboratories Co., Ltd.
557 Ramintra Rd., Bangkok, Thailand.

Product Registration Holder:
Delfi Marketing Sdn. Bhd.
Level 6, Block A, Sky Park One City,
Jalan USJ 25/1, 47650 Subang Jaya,
Selangor, Malaysia.

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