SCHEDULING STATUS: **S0**

PROPRIETARY NAME: **ADCO-SCRIPTO-LYTE**

(AND DOSAGE FORM) **(SOLUTION)**

COMPOSITION:

Each 30 ml of undiluted solution contains:

Potassium chloride.....335,8 mg

Sodium citrate .....469,8 mg

Sodium chloride .....473,68 mg

Dextrose monohydrate (sugar) .....3,96 g

Preservatives:

Methylparaben .....0,125 % m/m

Propylparaben.....0,025 % m/m

Each litre of diluted solution contains:

Sodium ..... 71,616 mmol..... 71,616 mEq

Chloride..... 70,000 mmol..... 70,000 mEq

Potassium..... 25,000 mmol..... 25,000 mEq

Citrate..... 8,872 mmol..... 8,872 mEq

Dextrose (sugar) ... 111,000 mmol..... 111,000 mEq

PHARMACOLOGICAL CLASSIFICATION:

A 24 Mineral substitutes, electrolytes

PHARMACOLOGICAL ACTION:

A glucose-electrolyte mixture which, when diluted with water as directed, replenishes electrolytes and fluids.

INDICATIONS:

Prevention and treatment of dehydration and electrolyte depletion associated with diarrhoea and gastroenteritis.

CONTRAINDICATIONS:

Severe diarrhoea where parenteral fluid therapy is required. Patients with glucose-galactose malabsorption syndrome. Anuric patients.

WARNINGS:

Contact a doctor, health professional, local clinic or hospital if the infant cannot take fluid by mouth, or is becoming weaker and dehydrated or if severe diarrhoea continues for 12 hours. Care should be exercised when the formulation is given to patients with renal failure and diabetes insipidus.

DOSAGE AND DIRECTIONS FOR USE:

1. The oral rehydration solution should be administered with a method that the infant is familiar with e.g. baby bottle, cup or spoon. Breast-feeding mothers may choose any of the aforementioned methods to administer the solution to their infants.
2. **ADCO-SCRIPTO-LYTE** should be given in addition to and in between normal feeds/meals in small, frequent and slowly administered amounts.

DILUTE BEFORE USE. Dilute six medicine measures (30 ml) with ¾ cup (150 ml) of water which has been previously boiled and cooled.

Infants less than one year of age should be given ½ to 1 cup (100 TO 200 ml) of **ADCO-SCRIPTO-LYTE** (diluted) for every time their bowels work.

Children 1 to 5 years of age should be given at least one cup (200 ml) for every time their bowels work.

Older children and adults should drink enough **ADCO-SCRIPTO-LYTE** to quench their thirst and replace fluid lost in every stool. If fluid volumes and body mass can be measured the following doses can be used instead of those above and a nasogastric tube can be used to administer **ADCO-SCRIPTO-LYTE.**

Maintenance of hydration in patients who are unable to take their usual feeds/meals :

Infants less than 1 year of age	120 ml/kg/day
Children 1 year to 2 years of age	100 ml/kg/day
Children older than 2 years and up to 4 years of age	85 ml/kg/day
Children older than 4 years and up to 10 years of age	70 ml/kg/day
Children older than 10 years of age and adults	2 to 3 L/day

Rehydration in mild dehydration: 50 ml/kg body mass over the first 6 hours, followed by maintenance therapy.

Rehydration in moderate to severe dehydrations: 100 ml/kg body mass over the first 6 hours, followed by maintenance therapy. Patients with moderate to severe dehydration are preferably rehydrated via the intravenous route with specially formulated intravenous dextrose-electrolyte solutions.

Ongoing losses: For every stool passed 10 to 20 ml/kg body mass should be given in addition to and in between normal feeds/meals.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Glucose intolerance may occur in some patients with diarrhoea.

Sodium salts should be used with caution in patients with cardiac failure, hypertension, impaired renal function, peripheral and pulmonary oedema. Potassium should be given with caution to patients with renal or adrenal insufficiency, acute dehydration or heat cramps as well as patients receiving potassium sparing diuretics.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage of glucose may cause nausea and vomiting. Overdosage of sodium may cause hypernatraemia, symptoms of which may include restlessness, weakness, thirst, reduced salivation and lachrymation, swollen tongue, flushing of the skin, pyrexia, dizziness, headache, oliguria, hypotension, tachycardia, delirium, hyperpnoea and respiratory arrest. Overdosage with potassium may cause hyperkalaemia with paraesthesia of the extremities, listlessness, mental confusion,

weakness, paralysis, hypotension, cardiac arrhythmias, heart block and cardiac arrest. Treatment is symptomatic and supportive.

IDENTIFICATION:

Clear, pale red solution. Odour of strawberry. Taste of saline and of strawberry.

PRESENTATION:

100 ml, 200 ml and 500 ml in clear PVC bottles or amber bottles and 2,5 L and 20 L in polycans.

STORAGE INSTRUCTIONS:

Store in a cool place below 30 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

E/24/1678

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