SCHEDULING STATUS: **S0**

PROPRIETARY NAME: **ADCO-ENTEROLYTE**
(AND DOSAGE FORM) **(SUSPENSION)**

COMPOSITION:

Each 30 ml contains:	
Kaolin	6 000,0 mg
Pectin	120,0 mg
Potassium chloride	41,4 mg
Sodium chloride	78,9 mg
Sodium lactate	86,4 mg
Preservatives:	
Methylparaben	0,20 % m/v
Propylparaben	0,02 % m/v

Sugar free.

PHARMACOLOGICAL CLASSIFICATION:
A 11.9 Antidiarrhoeals

PHARMACOLOGICAL ACTION:
ADCO-ENTEROLYTE exhibits intestinal adsorbent properties.

INDICATIONS:
ADCO-ENTEROLYTE is indicated for use as an adjunct to rest, electrolyte-containing fluids and appropriate diet in the symptomatic treatment of mild to moderate acute diarrhoea.

CONTRAINDICATIONS:
Intestinal obstruction. Hypersensitivity to any of the ingredients. The safety of **ADCO-ENTEROLYTE** for use during pregnancy and lactation has not been established. Not recommended for use in children under the age of 3 years.

WARNINGS:
The absorption of other agents from the gastrointestinal tract can be reduced if administered concomitantly with **ADCO-ENTEROLYTE**.

The electrolytes contained in this product are not intended as fluid replacement therapy.

DOSAGE AND DIRECTIONS FOR USE:

Adults and adolescents: 60 to 80 ml three to four times daily
Children 12 years and over: 60 ml three to four times daily
Children 6 to under 12 years: 30 to 40 ml three to four times daily
Children 3 to under 6 years: 15 to 20 ml three to four times daily

If the symptoms persist for longer than 48 hours or the condition of the patient deteriorates, the treatment must be discontinued, and a doctor consulted. In the treatment of diarrhoea it is important that hydration be maintained by administering adequate fluids and electrolytes.
Shake the bottle before use.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Constipation may occur.
The adsorbant properties of kaolin may influence the gastrointestinal absorption of other agents.
Potassium chloride may cause nausea, vomiting, diarrhoea, abdominal cramps and intestinal ulceration. Potassium solutions should be administered by mouth in well-diluted solutions.
Potassium salts should be given cautiously to patients with renal or adrenal insufficiency, acute dehydration, or heat cramp. Sodium salts should be administered with caution to patients with congestive heart failure, peripheral or pulmonary oedema, impaired renal function, or pre-eclampsia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Hyperkalaemia may occur after excessive intake of potassium chloride. Symptoms include paraesthesia of the extremeties, listlessness, mental confusion, weakness, paralysis, hypotension, cardiac arrhythmias, heartblock and cardiac arrest.
In hyperkalaemia, potassium containing foods and medications must be discontinued and potassium sparing diuretics withdrawn.
General adverse effects of excess sodium in the body include nausea, vomiting, diarrhoea, abdominal cramps, thirst, reduced salivation and lacrimation, sweating, fever, tachycardia, hypertension, renal failure, peripheral and pulmonary oedema, respiratory arrest, headache, dizziness, restlessness, irritability, weakness, muscle twitching and ridgidity, convulsions, coma and death. Excessive administration of sodium chloride causes hypernatraemia, the most serious effect of which is dehydration of internal organs, especially the brain. Excess chloride in the body may cause a loss of bicarbonate with an acidifying effect.

In the event of recent acute ingestion of sodium chloride, induction of emesis or gastric lavage should be carried out along with general symptomatic and supportive treatment.

IDENTIFICATION:

An off-white suspension with a characteristic banana odour and taste.

PRESENTATION:

Glass or plastic bottle containing 100 ml, 200 ml, and plastic bottle containing 2,5 L.

STORAGE INSTRUCTIONS:

Store below 25 °C. Keep well-closed.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

E/11.9/1688

NAME AND BUSINESS ADDRESS OF HOLDER OF THE CERTIFICATE OF REGISTRATION:

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