1. NAME OF THE MEDICINAL PRODUCT

Alben ORS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:
Anhydrous Glucose B.P..... 20g
Sodium Chloride B.P..... 3.5g
Sodium Citrate B.P..... 2.9g
Potassium Chloride B.P..... 1.5g

Excipients with known effect:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

- Powder for oral administration.
- White powder
- The solution is clear and colourless and a taste of Orange.

4. Clinical Particulars

4.1 Therapeutic indications

For the treatment of acute diarrhoea and the treatment and prevention of dehydration by replacing fluids and electrolytes lost through diarrhoea.

4.2 Posology and method of administration

A. Oral Rehydration Salts Reconstitution:

Only with water and at the volume stated.

Adults and children: The content of sachet should be dissolved in approximately 1000 ml of cool, fresh, clean drinking water. The resulting solution is both clear and colourless.

Infants: The water should be boiled then cooled before reconstitution as above. The reconstituted cooled solution should be used immediately and the unused remainder discarded, or stored in a refrigerator for no longer than 24 hours. Do not boil after reconstitution. The product must only be used at the recommended dilution.

Dosage: Oral fluid replacement and maintenance therapy must be tailored to individual patient's needs. The volume of solution used will depend on the weight and age of the patient, using the basic principle of firstly rehydrating the patient by replacing lost fluid and thereafter maintaining fluid replacement in line with the volume of fluid lost from stools or vomiting plus normal daily requirements. As a basic guide, a daily intake of 150 ml/kg bodyweight for infants (under 2 years of age) or 20-40ml/kg for adults and children is needed.

Replacement of fluid losses with ORS solution
Infants (under 2 years of age):

See special warnings and precautions for use. Sachets according to directions and administer at 1-1.5 times usual feed volume. No milk (other than breast milk) or solids should be given during the first 24 hours. In breastfed infants, ORS should be given before the feed. The re-introduction of normal feeding should only take place when symptoms of diarrhoea are abating and should be added gradually to make up the total daily fluid requirements.

Below 6 months: 1–1½times usual feed volume to be given Child
6 months–3 years: 200 mL-400mL, to be given after every loose motion
3Years–5 years: 400–800 mL, to be given after every loose motion, dose according to fluid loss
5years and above: One Litre, to be given after every loose motion, dose according to fluid loss.

In adults and children ORS can be given in amounts necessary to satisfy thirst. As with infants, solids should be avoided during the first day, but may be gradually resumed as necessary during day 2.
It is extremely difficult to over-hydrate by mouth, thus when there is normal renal function, it is better to give more ORS than less.

4.3 Contraindications

Hypersensitivity to any of the ingredients. Oral treatment is inappropriate in such conditions as severe dehydration, which requires parenteral fluid therapy or intestinal obstruction. It is necessary for medical supervision in the presence of renal disease, including anuria or prolonged oliguaria, severe and persistent diarrhea and vomiting, inability to drink or retain oral fluids.

4.4 Special warnings and precaution for use

Severe and persistent diarrhoea should be treated under medical supervision. If symptoms persist for more than 24 — 48 hours, medical advice should be sought. Inability to drink or retain fluids requires medical supervision.

Children

• Rehydration treatment should only be given to children under 1 year of age on medical advice.

• If a young child (particularly one under 6 months of age) has diarrhoea and/or vomiting advice should be sought from a pharmacist, doctor or other health care professional. If the diarrhoea and/or vomiting is severe the child should be seen by a doctor as soon as possible.

Renal Impairment

• Medical supervision is necessary in patients with renal disease, including anuria and prolonged oliguria.

Hepatic Impairment : Low potassium or Sodium diets: Diabetes

• Treatment should be supervised by a physician. This product contains dextrose. Patients with rare-glucose-galactose malabsorption should not take this medicine.

4.5 Interactions with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and Lactation

May be used during pregnancy and lactation as there are no known adverse effects. The safety of this product in human pregnancy has not been established.

4.7 Effects on ability to drive and use machines

ORS could not be expected to affect the ability to drive or use machines.

4.8 Undesirable effects

None stated.

4.9 Overdose

If significant over dosage occurs, serum and electrolytes should be evaluated. Corrective measures should be carried out and levels monitored until a return to normal levels is achieved.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

The product consists of physiological salts and glucose, which are used synergistically in solution to aid rehydration. The pharmacodynamic effect is to counter the drop in the extracellular fluid volume and electrolytes in mild to moderate diarrhoea. Pharmacotherapeutic group: Other mineral supplements, ATC code: A12CB01

5.2 Pharmacokinetic properties

Sodium and glucose are actively transported via the membrane into the enterocytes. Sodium is then extruded into the intercellular spaces and the resulting osmotic gradient causes water and electrolytes to be drawn from the gut and then into the circulation.

5.3 Preclinical safety data

None stated.

6. Pharmaceutical particulars

6.1 List of excipients

- Colloidal SiliconDioxide
- Orange Flavour Powder

6.2 Incompactibilities

- None Known.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

- Store in a cool dry place below 30°C. Keep medicine away from reach of children.

6.5 Nature and contents of container<and special equipment for use, administration or implantation>

27.9g powder packed in laminate sachet. Three foil laminate sachets in a monocarton.

6.6 Special precautions for disposal<and other handling>

None stated.

Applicant/Manufacturer

- Name: Alben Healthcare Industries Limited.
- Address: Km 15 Old Onitsha-Awka Road Ogidi, Anambra State, Nigeria.
- Phone No: 08068056661.
- Email Address:albenng@rocketmail.com.