ZOZO® ORS

SUBMITTED BY

NALIS PHARMACEUTICALS LTD

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE DRUG PRODUCT

Name of product; ZOZO® ORS (Oral Rehydration Salt 20.5 g)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 20.5 g contains:

Anhydrous Glucose BP	**13.500 g**
Sodium Chloride BP	**2.600 g**
Trisodium Citrate dihydrate BP	**2.900 g**
Potassium Chloride BP	**1.500 g**
Flavour: Orange Powder	**0.100 g**

Excipients with known effect
For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral powder

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Zozo® ORS indicated for the treatment of acute diarrhea and the treatment and prevention of dehydration by replacing fluids and electrolytes lost through diarrhoea.

4.2 Posology and method of administration

Posology

Adults, the elderly and children over 12 years
The contents of one or two sachets to be taken after each loose motion.

Children 1 to 12 years:
The contents of one sachet to be taken after each loose motion.

Infants under 1 year:
Not to be given unless instructed by a doctor, in which case one to one and a half the usual 24 hour feed volume should be given.

Reconstitution
The contents of each sachet should be dissolved in 200 ml (7 fluid ounces) of fresh drinking water (adults and children).
Freshly boiled and cooled water should be used for infants and when fresh water is not available. The solution should be made up immediately before use and used within one hour. If refrigerated the solution can be kept for up to 24 hours. A doctor should be consulted if symptoms persist for longer than 24 – 48 hours.

Method of Administration
For oral administration

4.3 Contradindications

Contraindicated in patients with phenylketonuria or those with hypersensitivity to any of the ingredients.
Oral treatment is inappropriate in such conditions as severe dehydration, which requires parenteral fluid therapy or intestinal obstruction.

4.4 Special warnings and precautions 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 n**ecessary 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 Interaction with other drug products and other forms of interaction

Sodium Bicarbonate
Increases excretion of lithium, resulting in a reduced plasma-lithium concentration.

Potassium Chloride
ACE inhibitors (hyperkalemia); cyclosporine (increased risk of hyperkalemia).
Potassium sparing diuretics where hyperkalemia may result. No known interactions to other actives

4.6 Fertility, pregnancy and lactation

May be used during pregnancy and lactation as there are no known adverse effects.

4.7 Effects on ability to drive and use machines

Zozo ORS have no influence on the ability to drive and use machines.

4.8 Undesirable effects

None stated.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the regulatory bodies such as NAFDAC.

4.9 Overdose

If significant overdosage 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

Pharmacotherapeutic group: Electrolytes with Carbohydrates
ATC Code: A07CA

The reconstituted solution contains a mixture of sodium and potassium salts along with glucose, which facilitates the absorption of sodium and potassium from the intestine. Water is drawn from the bowel by the osmotic effect. As well as "drying up" the stools, the dehydration and loss of electrolytes caused by the diarrhea is corrected by the water and electrolytes absorbed.

5.2 Pharmacokinetic properties

Glucose
After oral administration glucose is completely absorbed by a sodium dependent uptake mechanism exhibiting saturation kinetics. Blood levels return to normal within two hours of ingestion.

Potassium Chloride
No specific control mechanisms limit absorption of potassium, which is usually complete. Potassium is excreted largely by the kidneys, though 10% is excreted by the colonic mucosa. Potassium excretion is reduced in patients with renal impairment and in the elderly, so extreme caution should be used in treating such patients with potassium salts.

Sodium Bicarbonate
Kinetics are determined by the physiological state of the patient at the time.

Sodium Chloride
Readily absorbed from the gastrointestinal tract. Gut absorption, particularly in the jejunum is enhanced by the addition of glucose. Under conditions of sodium balance, the excretion of sodium in the urine will match intake.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Flavour: Orange Powder

6.2 Incompatibilities

None known

6.3 Shelf life

Three years

6.4 Special precautions for storage

Store below 30°C and away from light and moisture

6.5 Nature and contents of container

20.5 gm powder packed in aluminum foil sachet. Such sachets are packed in carton along with an insert.

6.6 Special precautions for disposal of used medicinal product or waste materials derived from such medicinal product and other handling of the product

None

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

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8. DRUG PRODUCT MANUFACTURER

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9. NAFDAC REGISTRATION NUMBER(S):

Not available