1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PRODUCT NAME: Oral Rehydration Salts BP

BRAND NAME: Ytalyte ORS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PRODUCT NAME: Oral Rehydration Salts

Each sachet contains:
Sodium chloride …….....2.60 g
Potassium chloride ……..……1.50 g
Sodium Citrate……2.90 g
Glucose (Dextrose) Anhydrous……13.50 g

For complete list of excipients(s) refer section 6.1.

3. PHARMACEUTICAL FORM:

White granular powder packed in Aluminium sachet

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication:

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

4.2 Posology and method of administration:

Each sachet for 1000 ml of water

Dosage: Depending on age and severity of dehydration

Infants & Children: 1-2 liters (5-10 Glasses) over a period of 24 hours.

Adults: 2-4 liters (10-20 glasses) over a period of 24 hours.

Continue treatment until diarrhea stops / dehydration is corrected. Caution: Depressed renal function. Severe continuing diarrhea or other critical fluid losses may need supplementation with other parenteral fluids with Ytalyte.

ORS Reconstitution
The contents of each sachet should be dissolved in 1000 ml 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 Contraindications:
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 warning 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 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 Drug Interactions

None stated.

4.6 Pregnancy &Lactation

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

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Product Name: Ytalyte ORS (Sodium chloride 2.6g + Potassium chloride 1.5g + Sodium citrate 2.9g + Glucose Anhydrous 13.5 BP

4.7 Effects on ability to drive and use machines:

None stated.

4.8 Adverse Effects

None stated.

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.

5.0 PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamics 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.

5.2 Pharmacokinetic properties

None relevant.

5.3 Preclinical Safety Data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

List of Excipient(s):

- Sweet orange dry powder DC

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months.

6.4 Special precautions for storage:

Do not store above 30°C.
Keep the medicine out of reach of children.

6.5 Nature and contents of container

20.5 g x 3 Aluminium sachet packed in clinical cartons

6.6 Special precautions for disposal and other handling
Any unused product or waste material should be disposed of in accordance with local requirements

7. APPLICANT

Name of the Applicant:
SAGAR VITACEUTICALS NIGERIA LIMITED.
Plot 6, New Makun City,
Along Lagos/Ibadan expressway,
K/m 53/55 Sagamu.
Ogun State,
NIGERIA

Manufactured by:
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NIGERIA

8. WHO PREQUALIFICATION REFERENCE NUMBER
Not applicable

9. DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION
Not applicable

10. DATE OF REVISION OF THE TEXT
Not applicable