SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINALPRODUCT

Afrab Oral Rehydration Salt

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each sachet contains
Glucose Anhydrous BP 13.5g
Sodium Citrate BP 2.9g
Sodium Chloride BP 2.6g
Potassium Chloride BP 1.5g

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

A light orange,orange flavoured crystalline powder

4. Clinical particulars

4.1 Therapeutic indications

Afrab Oral rehydration salt is used for rehydration from acute diarrhea and cholera.

4.2 Posology and method ofadministration

Posology

Each sachet to be diluted in 1 litre of clean water.

Dosage.

Infant and children: 0.5 litre - 1 litre daily
Adult: 2 - 4 litres daily

Method of administration

Afrab Oral rehydration salt is Granules to be reconstituted for oral administration.

Each sachet to be diluted in 1 litre of clean water.

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 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 necessary in patients with renal disease, including anuria and prolonged oliguria.

Hepatic Impairment : Low potassium or Sodium diets: Diabetes

4.5 Interaction 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.

4.7 Effects on ability to drive and use machines
None stated

4.8 Undesirable effects

None known

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 PHARMACEUTICALPARTICULARS

6.1 List of excipients

Aspartame

Orange flavour
Sunset yellow colour

6.2 Incompatibilities

None known.

6.3 Shelf life

The granules have a three year shelf life.

The reconstituted solution should be discarded after 24 hours if stored in a refrigerator

6.4 Special precautions for storage

Store below 30°

6.5 Nature and contents of container

Foil laminate sachet of 3 in a pack

6.6 Special precautions for disposal

No special requirements.

7 APPLICANT/MANUFACTURER

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