Drugfield Pharmaceuticals Limited

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Oral Rehydration Salt BP 20.6g

1. NAME OF THE MEDICINAL PRODUCT

Oral Rehydration Salt BP 20.6g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Glucose Anhydrous	BP	13.5 g
Sodium Chloride	BP	2.6 g
Potassium Chloride	BP	1.5 g
Trisodium Citrate Anhydrous	BP	2.9 g
Aspartame	BP	0.0267 g
Orange Flavour	BP	0.0493 g
Sunset Yellow	BP	0.0240 g

3. PHARMACEUTICAL FORM

Granules to be reconstituted for oral administration.

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

Depending upon the age and the severity of dehydration

Infants and children:

1-2 litres (5-10 glasses) over a period of 24 hours

Adults:

1-4 litres (10-20 glasses) over a period of 24 hours
Continue treatment until diarrhea stops/dehydration is corrected.

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

• 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 medicinal products and other forms of interaction

Not Applicable

4.6 Fertility, Pregnancy and Lactation

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

4.6 Effects on ability to drive and use machines

Not Applicable

4.8 Undesirable effects

Not Applicable

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 Pharmacological 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

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Not Applicable

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months.

The reconstituted solution should be discarded after 1 hour or 24 hours if stored in a refrigerator.

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture.

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

Foil laminate sachets

or

paper (outer surface layer) /polyethylene (outer layer) /aluminium foil (outer layer) /ionomer resin (inner layer) sachets

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/MANUFACTURER

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