SMPC FOR ORAL REHYDRATED SALT

1. Name of the medicinal product

ORAL REHYDRATED SALT

2. Qualitative and quantitative composition

Each sachet contains:

Anhydrous Glucose	BP
Sodium Chloride	BP
Sodium Citrate	BP
Potassium Chloride	BP

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

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.

During the first 24 hours of illness Jessy ORS should replace normal feeds in bottle fed babies, gradually resuming normal feeds as the baby gets better. In breast fed babies, firstly the recommended amount of Jessy ORS should be given and then breast fed until satisfactory.

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.

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.

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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
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 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. 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.

5.2 Pharmacokinetic properties
None relevant.

5.3 Preclinical safety data
None stated.

6. Pharmaceutical particulars

6.1 List of excipients
Aerosil 200

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Colouring Agent

6.2 Incompatibilities
None stated.

6.3 Shelf life
The granules have a two-year shelf life.

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 35°C in a dry place.

6.5 Nature and contents of container
Foil laminate sachets

6.6 Special precautions for disposal and other handling
None stated.

7. Marketing authorisation holder

UCGOD PHARMACEUTICAL LIMITED

8. Manufacturer: Daily sun pharmaceutical company Limited

9. Marketing authorisation number(s)

10. Date of first authorisation/renewal of the authorisation

29/09/2022

11. Date of revision of the text

28/09/2027