SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Rehydration Treatment
Superdrug Blackcurrant Flavour Rehydration Treatment
Morrison's Rehydration Treatment Granules for Oral Solution
Galpharm Lost Fluid Replacement Granules for Oral Solution
Sainsbury's Healthcare Rehydration Treatment Granules for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Dextrose Monohydrate	BP	3.580 g
Sodium Chloride	BP	0.470 g
Sodium Citrate Dihydrate	BP	0.390 g
Potassium Chloride	BP	0.300 g
Citric Acid Anhydrous	BP	0.128 g

Excipients with known affect

Each sachet contains:

Aspartame (E951) 10mg

For the full list of excipients, see section 6.1

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, rehydration treatment 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 rehydration treatment should be given and then breast fed until satisfactory.

Reconstitution: The contents of each sachet should be dissolved in 200ml (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.

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 medicine contains 10 mg aspartame in each sachet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.

4.5 Interaction with other medicinal products and other forms of interaction

None stated

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

None stated

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 via the Yellow Card Scheme at:www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

Colloidal Anhydrous Silica BP

Aspartame (which contains Phenylalanine)

Blackcurrant Flavourings

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 25ºC in a dry place

6.5 Nature and Contents of Container

Foil laminate sachets

or

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

Pack sizes of 5, 6, 10, 12 and 20 sachets

6.6 Special precautions for disposal

None stated

7 MARKETING AUTHORISATION HOLDER

Wrafton Laboratories Ltd

Wrafton

Braunton

North Devon

EX33 2DL

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 12063/0046

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/11/2003

10 DATE OF REVISION OF THE TEXT

20/04/2022