

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Rehydration Treatment Granules for Oral Solution  
Salio Granules for Oral Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Dextrose (glucose) monohydrate	3.58g
Sodium chloride	0.47g
Potassium chloride	0.30g
Sodium citrate dihydrate	0.39g
Anhydrous citric acid	0.128g

Excipient with known effect: Also contains 10 mg of aspartame

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

Posology

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 one to one and a half times 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 satisfied.

#### Reconstitution

The contents of each sachet should be dissolved in 200ml (7 fluid ounces) of fresh drinking water (for both 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 1 hour. If refrigerated the solution may be kept for up to 24 hours.

A doctor should be consulted if symptoms persist for longer than 24 – 48 hours.

### **4.3 Contraindications**

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Oral treatment is inappropriate in such conditions as severe dehydration, which requires parenteral fluid therapy or intestinal obstruction.
- Contraindicated in patients with phenylketonuria.

### **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 medicinal product contains dextrose. Patients with rare-glucose-galactose malabsorption should not take this medicine.

#### **Important information regarding the ingredients of this medicine**

Sodium: This medicinal product contains 276.46 mg sodium per sachets, equivalent to 13.82% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Potassium: This medicine contains 159.94mg potassium per sachet . To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

#### **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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### **4.9 Overdose**

If significant over dosage occurs, serum and electrolytes should be evaluated. Corrective measures should be carried out and levels monitored until a return to normal level 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 2 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 25°C in a dry place.

#### **6.5 Nature and contents of container**

Single dose foil laminate sachets enclosed in a cardboard outer containing 6, 10, 20, 50 or 100 sachets.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for disposal and other handling**

**Reconstitution:** The contents of each sachet should be dissolved in 200ml (7 fluid ounces) of fresh drinking water (for both 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 1 hour. If refrigerated the solution may be kept for up to 24 hours.

Solutions other than water should not be used for reconstituting the product and each sachet should be dissolved in the correct volume as above.

### **7 MARKETING AUTHORISATION HOLDER**

Bristol Laboratories Ltd  
Unit 3, Canalside  
Northbridge Road  
Berkhamsted  
Herts  
HP4 1EG

### **8 MARKETING AUTHORISATION NUMBER(S)**

PL 17907/0462

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

7<sup>th</sup> April 2003

**10 DATE OF REVISION OF THE TEXT**

20/09/2023