

**1.3.1**  
**Summary Of Product Characteristics (SPC)**

### **1.3.1 Summary of Product Characteristics**

#### **1.3.1.1 Invented Name of the Medicinal Product**

**G-ORAL**

Oral Rehydration Salts BP

#### **1.3.1.2 Strength**

Sodium Chloride BP ..... 2.60 gm  
Potassium Chloride BP ..... 1.50 gm  
Sodium Citrate BP ..... 2.90 gm  
Anhydrous Glucose BP ..... 13.50 gm

#### **1.3.1.3 Pharmaceutical Form**

Powder for Oral Solution

#### **1.3.1.4 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each sachet Contains (to produce 1000 ml):

Sodium Chloride BP ..... 2.60 gm  
Potassium Chloride BP ..... 1.50 gm  
Sodium Citrate BP ..... 2.90 gm  
Anhydrous Glucose BP ..... 13.50 gm  
Excipients..... Q. S.

Colour & Flavour added

For a full list of excipients see section 1.3.1.8.1

#### **1.3.1.5 PHARMACEUTICAL FORM**

Powder for Oral solution

Light orange coloured free flowing powder.

### **1.3.1.6 CLINICAL PARTICULARS**

#### **1.3.1.6.1 Therapeutic indications**

G-ORAL is indicated for:

- Oral correction of fluid and electrolyte loss in infants, children and adults.
- Treatment of watery diarrhoea of various aetiologies including gastro-enteritis, in all age groups.

#### **1.3.1.6.2 POSOLOGY AND METHOD OF ADMINISTRATION**

##### **Posology**

**Route of Administration:** Oral

##### **Method of Reconstitution:**

Dissolve entire content on one sachet in litre of boiled and cooled water.

A basic principle of treatment of diarrhoea is to replace lost fluid and electrolytes and then to maintain sufficient fluid intake to replace fluid loss from stools. The amount of reconstituted Oral Rehydration Salts administered should be adapted to the age and weight of the patient and the stage and severity of the condition.

Severe dehydration may need to be corrected by parenteral fluids initially, followed by oral maintenance if indicated. If the loss of fluid in the diarrhoea is excessive, medical advice should be sought.

Daily intake may be based on a volume of 150ml/kg body weight for infants up to the age of 2 and 20-40ml/kg body weight for adults and children. A reasonable approximation is:

Infants: One Litre over 24 hours period.

Child: One litre over 6-24 hours period, according to age

Adult: Drink freely as required.

More may be required initially to ensure early and full volume repletion.

In the initial stages of treatment of diarrhoea all foods, including cow's or artificial milk, should be stopped. However breast milk need not be withheld. In breast fed infants it is suggested that the infant is given the same volume of Oral Rehydration Salts as the bottle fed baby and then put to the breast until satisfied. Expression of residual milk from the

breasts may be necessary during this period. After 24 - 48 hours, when symptoms have subsided, the normal diet should be resumed but this should be gradual to avoid exacerbation of the condition.

When vomiting is present with the diarrhoea it is advisable that small amounts of Oral Rehydration Salts be taken frequently. However, it is important that the whole of the required volume of Oral Rehydration Salts be taken. Where the kidneys are functioning normally, it is difficult to over-hydrate by mouth and where there is doubt about the dosage, more rather than less should be taken. If no improvement is seen within 24-48 hours it is recommended that the patient be seen by a physician.

#### **1.3.1.6.3 CONTRAINDICATIONS**

There are no known contraindications to Oral Rehydration Salts. However, there may be a number of conditions where treatment with Oral Rehydration Salts will be inappropriate e.g. intestinal obstruction requiring surgical intervention.

#### **1.3.1.6.4 WARNING AND PRECAUTIONS**

For oral administration only.

Oral Rehydration Salts should not be reconstituted in diluents other than water. Each Sachet should always be dissolved in 1000ml of water. A weaker solution than recommended will not contain the optimal glucose and electrolyte concentration and a stronger solution than recommended may give rise to electrolyte imbalance. If diarrhoea persists unremittingly for longer than 24-48 hours the patient should be seen by a physician. Oral Rehydration Salts should not be used for the self-treatment of chronic or persistent diarrhoea except under medical supervision. Infants under the age of 2 years with diarrhoea should be seen by a physician as soon as possible. No specific precautions are necessary in the elderly.

Oral Rehydration Salts should not be used for self-treatment by patients with liver or kidney disease, patients on low potassium or sodium diets or patients with diabetes. The use of Oral Rehydration Salts in patients with these conditions should be supervised by a physician.

#### **1.3.1.6.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION**

Not Stated.

#### **1.3.1.6.6 PREGNANCY AND LACTATION**

##### **PREGNANCY:**

Oral Rehydration Salts is not contra-indicated in pregnancy or lactation.

#### **1.3.1.6.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

Oral Rehydration Salts could not be expected to affect the ability to drive or use machines.

#### **1.3.1.6.8 UNDESIRABLE EFFECTS**

Excessive use of oral rehydration salts may cause swelling of the limbs, sickness, diarrhea, Stomach pains, thirst, dry mouth, fever, headache, dizziness, restlessness, irritability, weakness, increased sodium and potassium levels

#### **1.3.1.6.9 OVERDOSE**

In electrolyte replacement therapy, toxicity is rare in previously healthy people. In subjects with renal impairment, hyponatremia and hyperkalemia might occur. In the event of significant overdose, serum electrolytes should be evaluated as soon as possible, appropriate steps taken to correct abnormalities and levels monitored until return to normal levels is established. This is particularly important in the very young and in cases of severe hepatic or renal failure.

### **1.3.1.7 PHARMACOLOGICAL PROPERTIES**

#### **1.3.1.7.1 Pharmacodynamic properties**

Oral Rehydration Salts is an oral rehydration therapy. The combination of electrolytes stimulates water and electrolyte absorption from the GI tract and therefore prevents or reverses dehydration in diarrhoea.

Sodium chloride/ Potassium chloride	Salts/Electrolytes
Sodium citrate	Acid Neutraliser
Glucose anhydrous	Carbohydrate electrolyte carrier.

#### **1.3.1.7.2 Pharmacokinetic properties**

Sodium and glucose are actively transported via the membrane into the enterocytes. Sodium is then extruded into the intercellular spaces and the resulting osmotic gradient causes water and electrolytes to be drawn from the gut and then into the circulation.

Glucose has been shown to greatly enhance the absorption of salts and water. The concentration used in Oral rehydration salts is very effective and has been demonstrated as giving a twenty five-fold enhancement of absorption compared with isotonic saline. Also, as the solution is more palatable, patient compliance is increased.

### **1.3.1.8 PHARMACEUTICAL PARTICULARS**

#### **1.3.1.8.1 List of excipients**

None

#### **1.3.1.8.2 Incompatibilities**

Not applicable.

#### **1.3.1.8.3 Shelf life**

36 months from the date of manufacturing.

**1.3.1.8.4 Special precautions for storage**

Store below 30°C. Protect from light.

Keep all medicines out of reach of children.

**1.3.1.8.5 Nature and contents of container**

G-ORAL is available as 3 sachets, packed in a printed carton.

**1.3.1.8.6 Special precautions for disposal and other Special handling**

None

**1.3.1.9 Marketed by:**

**GREENLIFE PHARMACEUTICAL LIMITED**

No.2 Bank lane. Off town Planning Way,

Ilupeju, Lagos – Nigeria.