

**Brand Name: G-ORAL PLUS**

**Generic Name: Combipack of Oral Rehydration Salts BP & Zinc Sulfate Tablets USP**

**Module 1**

**(Administrative File)**

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### **1.3.1**

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

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### **1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS**

#### **1.3.1.1. NAME OF THE MEDICINAL PRODUCT**

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

**G-ORAL PLUS**

Combipack of Oral Rehydration Salts BP & Zinc Sulfate Tablets USP

##### **1.3.1.1.2 Strength**

###### **ORAL REHYDRATION SALTS BP**

Sodium Chloride BP ..... 2.6 gm

Potassium Chloride BP ..... 1.5 gm

Sodium Citrate BP ..... 2.9 gm

Anhydrous Glucose BP ..... 13.5 gm

###### **ZINC SULFATE TABLETS USP**

Zinc Sulfate (Monohydrate) USP

Eq. to Elemental Zinc ..... 20 mg

##### **1.3.1.1.3 Pharmaceutical Form**

Oral Dosage form

#### **1.3.1.2. QUALITATIVE AND QUANTITATIVE**

##### **COMPOSITION Oral Rehydration Salts BP**

Each sachet of 20.5gm Contains:

Sodium Chloride BP ..... 2.6 gm

Potassium Chloride BP ..... 1.5 gm

Sodium Citrate BP ..... 2.9 gm

Anhydrous Glucose BP ..... 13.5 gm

Excipients..... Q. S.

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### **Zinc Sulfate Tablets USP 20 mg**

Each Dispersible Tablet contains:

Zinc Sulfate (Monohydrate) USP .....54.89 mg

Eq. to Elemental Zinc ..... 20 mg

Excipients ..... q. s.

For a full list of excipients see section 6.1

### **3. 1.3.1.3 PHARMACEUTICAL FORM**

Oral Dosage form

Oral Rehydration Salts: White crystalline powder.

Zinc Sulfate Tablets: White colour circular, flat uncoated dispersible tablets with break line on one side.

### **1.3.1.4 CLINICAL PARTICULARS**

#### **1.3.1.4.1 Therapeutic indications**

Oral Rehydration Salts is primarily indicated for the replacement of fluid & electrolytes and maintenance of hydration in diarrhea, vomiting, excessive sweating of varied etiology & other conditions where there is loss of water & electrolytes. :

Zinc sulfate is a source of zinc which is essential trace element and involved in a number of body me systems and used for the treatment of zinc deficiency.

#### **1.3.1.4.2 POSOLOGY AND METHOD OF ADMINISTRATION**

##### **Posology**

**Route of Administration:** Oral

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

**ORS:** Dissolve entire content on one sachet in one litre of freshly boiled and cooled water. Stir until powder is completely dissolved. Do not boil the solution after constitution. Use within 24 hours of reconstitution.

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**Zinc supplementation:** Zinc tablets must be given once a day and repeat every day until the course is complete. Zinc sulfate tablets may be dispersed in (5ml) breast milk or freshly boiled and cooled water on a tablespoon. Older children can swallow the tablet with 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.

**Dosage:**

Oral Rehydration Salts:

Infants: One Litre over 24 hours period.

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

Adult: Drink freely as required.

**Zinc supplementation:**

Adult: One tablet once daily.

Children (6 months – 12 years): One tablet once daily.

Children less than 6 months: Half (1/2) tablet should be dissolved in 5 ml of water once daily or as prescribed by the physician.

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.

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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.

#### **1.3.1.4.3 CONTRAINDICATIONS**

G-ORAL PLUS is contraindicated in patients who are hypersensitive to ORS and Zinc or any component of the product.

#### **1.3.1.4.4 WARNING AND PRECAUTIONS**

##### **Oral Rehydration Salts:**

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.

##### **Zinc supplementation:**

Zinc sulfate Tablets may interfere with uptake of certain antibiotics, penicillamine, Sodium valproate, ethambutol etc. Do not co-administer zinc sulfate tablets with above drugs.

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

Not Stated.

#### **1.3.1.4.6 PREGNANCY AND LACTATION**

**ORS:** The dose is same as adult dose. Breast feeding can be continued as normal. If vomiting is a problem then ORS solution should be taken in frequent small volumes.

ORS is not contraindicated in pregnancy or lactation but should be used on medical advice.

**ZINC:**

Pregnancy: The safety of Zinc sulfate tablets 20 mg in pregnancy has not been established.

Lactation: Zinc crosses the placenta and is present in breast milk. The safety of zinc sulfate tablets 20 mg in lactation has not been established.

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

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

#### **1.3.1.4.8 UNDESIRABLE EFFECTS**

Oral Zinc sulfate supplements can cause side effects such as heartburn and nausea. Rare side effects include fever, sore throat, mouth sores, weakness and fatigue. 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.

#### **1.3.1.4.9 OVERDOSE**

**Oral rehydration Salts:**

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

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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.

**Zinc supplementation:**

Zinc sulfate is corrosive in overdose. Symptoms are corrosion and inflammation of the mucous membrane of the mouth and stomach; ulceration of the stomach followed by perforation may occur. Gastric lavage and emesis should be avoided. Demulcents such as milk should be given. Chelating agents such as sodium calcium edetate may be useful.

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### **1.3.1.5. PHARMACOLOGICAL PROPERTIES**

#### **1.3.1.5.1 Pharmacodynamic properties**

##### **Oral Rehydration Salts:**

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.

##### **Zinc supplementation:**

Zinc is an essential trace element involved in many enzyme systems. Severe deficiency causes skin lesion, alopecia, diarrhea, increased susceptibility to infections and failure to thrive in children. Symptoms of less severe deficiency include distorted or absent perceptions of taste and smell and poor wound healing.

#### **1.3.1.5.2 Pharmacokinetic properties**

##### **Oral Rehydration salts:**

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.

##### **Zinc supplementation:**

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body. Plasma zinc levels range from 70 to 110 µg/dl and about 50% of this is loosely bound to albumin. About 7% is amino-acid bound and the rest is tightly bound to alpha 2-macroglobulins and other proteins.

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### **1.3.1.6. PHARMACEUTICAL**

#### **PARTICULARS 6.1 List of excipients**

Microcrystalline cellulose
Maize Starch
Lactose
Cross carmellose sodium
Polyvinyl pyrrolidone (PVPK-30)
Isopropyl Alcohol
Purified Talc
Sodium starch glycollate
Colloidal silicon dioxide
Kyron T 314
Flavour orange
Aspartame
Magnesium Stearate

#### **1.3.1.6.2 Incompatibilities**

Not applicable.

#### **1.3.1.6.3 Shelf life**

For both ORS and Zinc Tablets: 36 months from the date of manufacturing.

#### **1.3.1.6.4 Special precautions for storage**

Store below 30°C. Protect from light.

Keep all medicines out of reach of children.

#### **1.3.1.6.5 Nature and contents of container**

**G-ORAL PLUS** is available as 2 sachets of 20.5g each of ORS and two blister packs of 7 tablets, packed in a printed carton along with pack insert.

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**1.3.1.6.6 Special precautions for disposal and other Special handling** None

**1.3.1.7. Marketed by:**

**M/S. GREENLIFE PHARMACEUTICALS LTD.**

, 2, BANK LANE, OFF TOWN PLANNING WAY,  
ILUPEJU, LAGOS, NIGERIA.

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