**Summary of Product Characteristics for Pharmaceutical Products**

## 1. Name of the medicinal product:

Diors 500ml

## 2. Qualitative and quantitative composition

Each satchet (10.3 g) contains
Glucose BP (Anhydrous) 6.75 g
Sodium citrate BP 1.45 g
Sodium Chloride BP 1.30 g
Potassium Chloride BP 0.75 g

For the full list of excipients, see section 6.1.

## 3. Pharmaceutical form

Powder for Oral Solution,
White coloured crystalline powder.

## 4. Clinical particulars

### 4.1 Therapeutic indications

Oral rehydration salt is indicated for the treatment of acute diarrhea and the treatment and prevention of dehydration by replacing fluids and electrolytes lost through diarrhoea.

### 4.2 Posology and method of administration

The amount of reconstituted Diors should be adapted to the age, weight of the patient, stage and severity of the condition. Severe dehydration may need to be corrected by parenteral fluids initially, followed by oral maintenance if indicated.

**Daily intake;**
Based on volume of 150ml/Kg body weight for infants up to age of 2 years and 20-40 ml/kg body weight for adults and children;

**Adults, the elderly and children over 12 years:**
The contents of one or two sachets to be taken after each loose motion. Each sachet dissolved in 200ml of water.

**Children 1 to 12 years:**
The contents of one sachet to be taken after each loose motion. Each sachet dissolved in 200ml of water.

**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.

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 Diors 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.

**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. The solution itself should not be boiled. A doctor should be consulted if symptoms persist for longer than 24 – 48 hours.

**Method of administration**
For oral use

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

Diors should not be reconstituted in diluents other than water. The solution should not be boiled after preparation.

Administer with care in patients with acute heat cramps, extensive tissue destruction, patients receiving potassium sparing diuretics.

## 4.5 Interaction with other medicinal products and other forms of interaction

**Sodium Bicarbonate**
Increases excretion of lithium, resulting in a reduced plasma-lithium concentration.

**Potassium Chloride**
ACE inhibitors (hyperkalemia); cyclosporine (increased risk of hyperkalemia). Potassium sparing diuretics where hyperkalemia may result. No known interactions to other actives.

## 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

No studies on the effects on the ability to drive and use machines have been performed.

## 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 reconstituted solution contains a mixture of sodium and potassium salts along with glucose, which facilitates the absorption of sodium and potassium from the intestine. Water is drawn from the bowel by the osmotic effect. As well as "drying up" the stools, the dehydration and loss of electrolytes caused by the diarrhea is corrected by the water and electrolytes absorbed.

**Pharmacotherapeutic group:** Electrolytes with Carbohydrates
**ATC Code:** A07CA

### 5.2 Pharmacokinetic properties

**Glucose**

After oral administration glucose is completely absorbed by a sodium dependent uptake mechanism exhibiting saturation kinetics. Blood levels return to normal within two hours of ingestion.

**Potassium Chloride**

No specific control mechanisms limit absorption of potassium, which is usually complete. Potassium is excreted largely by the kidneys, though 10% is excreted by the colonic mucosa. Potassium excretion is reduced in patients with renal impairment and in the elderly, so extreme caution should be used in treating such patients with potassium salts.

**Sodium chloride**

Readily absorbed from the gastrointestinal tract. Gut absorption, particularly in the jejunum is enhanced by the addition of glucose. Under conditions of sodium balance, the excretion of sodium in the urine will match intake.

### 5.3 Preclinical safety data

Not applicable

## 6. Pharmaceutical Particulars

### 6.1 List of Excipients

Aspartame & Orange flavor powder

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf-Life

24 months

## 6.4 Special Precautions for storage

Store in a dry place below 30°C
Protect from light
Keep all medicines out of reach of children

## 6.5 Nature and Content of container

Printed foil
Pack size: 10.3 grams powder to make 500 ml solution.

## 6.6 Special precautions for disposal and other handling

No special requirements.

## 7. Marketing Authorization Holder

Dinlas Pharma (Africa) Limited
Mombasa Road, Syokimau
P.O Box 22661-00505
Nairobi-Kenya

## 8. Marketing Authorization Number

CTD10874

## 9. Date of first authorization/renewal of the authorization

Date of Registration: 15-09-2023

## 10. Date of revision of the text

10/05/2025