

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. Name of the medicinal product

VARIHYDRASALTS®

### 2. Qualitative and quantitative composition

Quantity per dosage unit g/l:

Sodium Chloride	2.6
Glucose Anhydrous	13.5
Potassium Chloride	1.5
Trisodium Citrate, dehydrate	2.9

### 3. Pharmaceutical form

Pale orange crystalline powder which produces a clear pale orange solution after reconstitution.

### 4. Clinical particulars

#### 4.1. Therapeutic indications

Vari-Hydrasalts® is indicated for the treatment of diarrhea and fluid loss due to diarrhea in infants, children, and adults.

Vari-Hydrasalts® Orange is particularly recommended in the case of too loose or frequent stools where it enables over-loose stools to revert to normal.

#### 4.2. Posology and method of administration

ORS (1L water = 20,5g Varihydrasalts® Orange)				
Age	Dosage	Water for solution	Duration	How often
Less than 2 years	1.3 – 2.6g Varihydrasalts® Orange powder	Between ¼ and ½ of a 250 millilitre cup	2 days	After each water y stool
Older than 2 years	2.6 – 5.1g Varihydrasalts® Orange powder	Between ½ and 1 whole 250 millilitre cup		

### PREPARATION

1. Boil and cool clean water.
2. Find and clean equipment: a 1L water bottle, cup and spoon.
3. Wash hands.
4. Measure the required clean boiled water, according to instructions on sachets.
5. Put the contents of the Varihydrasalts® Orange packet in a clean container.

Check the packet for directions and add the correct amount of clean water. Too little water could

make the diarrhoea worse. Add water only. Do not add Varihydrasalts<sup>®</sup> Orange to milk, soup, fruit juice or soft drinks. Do not add sugar.

6. Mix Varihydrasalts<sup>®</sup> Orange in the water.

Stir well, and feed it to the child from a clean cup. Do not use a bottle.

Varihydrasalts<sup>®</sup> Orange is best given by spoon to infants or cup for older children

#### **4.3. Contraindications**

Hypersensitivity to any of the ingredients.

Oral treatment is inappropriate in such conditions as severe dehydration, which requires parenteral fluid therapy or intestinal obstruction.

It is necessary for medical supervision in the presence of renal disease, including anuria or prolonged oliguria, severe and persistent diarrhoea and vomiting, inability to drink or retain oral fluids.

#### **4.4. Special warnings and precautions for use**

Infants under the age of 2 years with severe diarrhoea/vomiting should be seen by a doctor as soon as possible.

If symptoms persist for longer than 24-48 hours, a doctor should be consulted.

The solution must be made up without adding extra sugar or salt. In treating diabetics with gastro-enteritis, the sugar content must be noted.

Solutions of greater concentration may result in hypernatraemia. Those of greater dilution may result in inadequate replacement.

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

None known.

#### **4.6. Pregnancy and lactation**

The dose is the same as adult dose. Breast feeding can be continued as normal. If vomiting is a problem then Vari-hydrasalts<sup>®</sup> Orange solution should be taken in frequent small volumes. Vari-hydrasalts<sup>®</sup> Orange is not contraindicated in pregnancy or lactation but should be used on medical advice.

#### **4.7. Effects on ability to drive and use machines**

None known

#### **4.8. Undesirable effects**

None known..

#### **4.9. Overdose**

In the event of significant overdose, serum electrolytes should be evaluated as soon as possible, appropriate steps taken to correct any abnormalities and levels monitored until return to normal levels is established. This is particularly important in the very young.

### **5. Pharmacological properties**

#### **5.1. Pharmacodynamic properties**

Sodium Chloride and Potassium Chloride - Salts/

Electrolytes Glucose Anhydrous - Carbohydrate

Electrolyte carrier Trisodium citrate dehydrate - buffering agent or acidity regulator

#### **5.2. Pharmacokinetic properties**

The Vari-Hydrasalts<sup>®</sup> Orange formulation is based upon the well accepted WHO

oral rehydration solution (ORS).

Glucose has been shown to greatly enhance the absorption of salts and water. The concentration used in Varihydrasalts® Orange is very effective and has been demonstrated as giving a twenty five-fold enhancement of absorption compared with isotonic saline.

The level of sodium in Varihydrasalts® Orange reflects the stool concentration in most cases of severe diarrhoea. Also, as the solution is more palatable, patient compliance is increased. Potassium and Chloride are included to replace these electrolytes lost in the stool.

Trisodium citrate dehydrate is a buffering agent or acidity regulator

### **5.3.Preclinical safety data**

Not available

## **6. Pharmaceutical particulars**

### **6.1.List of excipients**

None

### **6.2.Incompatibilities**

None known.

### **6.3.Shelf life**

24 months

### **6.4.Special precautions for storage**

Store the medicine in a cool and dry place. Do not store above 30 °C. Dispose medicine that has been dissolved for more than 24 hours.

During treatment it is important to store the kit properly (in a cool and dry place).

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

Triple laminate aluminium foil of pack sizes 20.5g, 10.25g and 5.125g.

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

Not applicable.

## **Administrative data**

### **7.Principal and Manufacturer**

Varichem Pharmaceuticals (Pvt)

Ltd 194 Gleneagles Road

Willowvale

Harare

Tel: +263 (04) 620181-7

Fax: +263 (04) 660424

Email: [marketing@varipharm.co.zw](mailto:marketing@varipharm.co.zw)

## **8. Registration number(s)**

TAN 22 HM 0265

**9. Date of first authorization/renewal of authorization**

19<sup>th</sup> July, 2022

**10. Date of revision of the text**