

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

VARIHYDRASALTS® ORANGE FLAVOUR

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

Contains Sunset Yellow Supra (FD +C No.6)

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[®] Orange to milk, soup, fruit juice or soft drinks. Do not add sugar.
6. Mix Varihydrasalts[®] Orange in the water.
Stir well, and feed it to the child from a clean cup. Do not use a bottle.

Varihydrasalts[®] 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.

This medicinal product contains Sunset Supra Yellow (FD + C No.6)

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[®] Orange solution should be taken in frequent small volumes. Vari-hydrasalts[®] 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® 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

Sunset Yellow Supra (FD + C No. 6)
Orange Flavour Powder consisting of:
Maltodextrin (maize)
Sugar
Starch Modified Corn E1450

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

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

6.6. Special precautions for disposal and other handling

Not applicable.

7. Marketing authorization holder

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8. Marketing authorization number

TAN 22 HM 0266

9. Date of first authorization/renewal of authorization

19th July, 2022

10. Date of revision of the text