SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Minerali

2. Qualitative and quantitative composition

Each ml contains:

Glucose monohydrate	14.85 mg
Sodium Chloride	2.70 mg
Potassium Chloride	1.50 mg
Sodium Citrate	2.20 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Oral Solution

4. Clinical particulars

4.1 Therapeutic indications

For the prevention of dehydration by replacing fluids and electrolytes loss associated with conditions such as acute diarrhoea.

4.2 Posology and method of administration

It is advisable that small amounts of Minerali be taken frequently every few minutes.

During the first 2-4 hours the following dosage is recommended:

Fluid loss without dehydration symptoms (patient is alert, drinks normally, non-sunken eyes, tears present when crying, normal or reduced urine output, warm extremities, moist lips and tongue, pinched skin recoil instantly): 10 ml/kg body after each loose motion and 2 ml/kg after each vomiting episode.

In case the child weight is unknown:

Below 10 kg (below 2 years of age): 50 -100 ml after each loose motion or vomiting episode

10 kg and above (age 2-10 years): 100-200 ml after each loose motion or vomiting episode.

The patient should be encouraged to drink as much as wanted until condition is resolved.

Mild to moderate fluid loss: (patient is restless, irritable or fatigued, thirsty, slightly sunken eyes [in babies, anterior fontanel is slightly sunken], decreased tears when crying, decreased urine output, cool extremities, sticky or dry lips and tongue, pinched skin recoil slowly (<2 seconds): 50-100 ml/kg body weight.

In addition, 10 ml/kg body weight should be added after each loose motion and 2 ml/kg body weight after each vomiting episode.

In case the child weight is unknown:

Below 10 kg (below 2 years of age): add 50 -100 ml after each loose motion or vomiting episode
10 kg and above (age 2-10 years): add 100-200 ml after each loose motion or vomiting episode.

Sever fluid loss or sever illness condition (blood in stool (loose motion), loose motion for more than 48 hours, more than 5 vomiting episodes a day, temperature (fever) >39°c, apathetic, lethargic, drinks poorly or unable to drink, deeply sunken eyes [in babies- anterior fontanel is significantly sunken], no tears, dry lips and tongue, minimal urine output, cold cyanotic extremities): Refer to a physician

After 4 hours from treatment initiation, treatment and fluid loss symptoms should be re-assessed. If fluid loss symptoms still exist, treatment can be repeated until symptoms resolved. If symptoms get worse the patient should see a physician.

The solution is ready to use. No water or sugar should be added to the solution and it should not be mixed with other liquids. The solution can be refrigerated if prefer to be drank as cold solution.
The solution should be given in small amounts at short intervals. Small amount every few minutes.
Drinking the solution may causa vomiting or spitting-up. Mild vomiting doesn't interfere proper use of the solution.
If the child vomit or spit the solution should be given using a spoon or in small sips to improve absorption.

Breastfed and bottle fed babies: It is recommended to continue with regular feeding during the treatment. Minerali should be given at the recommended dose, and regular feeding should be initiated at the time of the first rehydration treatment with Minerali or immediately at the end of it, within 4-6 hours.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
  There are no known contraindications to Minerali. However, there may be a number of conditions where treatment with Minerali will be inappropriate e.g. intestinal obstruction requiring surgical intervention.

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. Minerali should not be used for the self treatment of chronic or persistent diarrhoea except under medical supervision.

Children
- Minerali can be given to children from 1 year of age.

- Minerali should only be given to children under 1 year of age on medical advice.
- Diarrhoea can have very serious consequences in children under 3 years old. Immediate medical advice should be sought.
- If the diarrhoea and/or vomiting is severe the child should be seen by a doctor as soon as possible.
- This medicinal product contains Sodium Benzoate, which may increase jaundice in newborn babies (up to 4 weeks old)

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

Minerali should not be used for self-treatment by patients:

- with chronic or persistent diarrhea.
- with liver or kidney disease.
- with diabetes.
- on low potassium or sodium diets.
- with an intestinal obstruction.

The use of Minerali in patients with these conditions should be supervised by a physician.

If nausea and vomiting are present with the diarrhoea, small but frequent amounts should be drunk at first.

- This medicinal product contains 160 mg sodium per 100 ml, equivalent to 8% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
- This medicinal product contains 79 mg potassium per 100 ml. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6. Pregnancy and lactation

Minerali is not contra-indicated in pregnancy or lactation.
Medical supervision is recommended for use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Minerali could not be expected to affect the ability to drive or use machines.

4.8 Undesirable effects

None stated.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:

https://sideeffects.health.gov.il

4.9 Overdose

In the event of significant overdose, serum electrolytes should be evaluated as soon as possible, appropriate steps taken to correct an 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 of renal failure.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Dioralyte 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

5.2 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.

5.3 Preclinical safety data

No relevant data.

6. Pharmaceutical particulars

6.1 List of excipients

Purified water
Phosphoric Acid Diluted 10%
Hydrochloride Acid 10%
Cherry Flavor
Citric Acid Anhydrous
Sorbic Acid
Sodium Cyclamate
Saccharin Sodium
Sodium Benzoate

6.2 Incompatibilities

None stated.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
Shelf life after first opening: 3 days after first opening.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

White bottle with a child resistant tamper screw PP cap which contains 500 ml clear, colorless to yellowish liquid with cherry odour.

6.6 Special precautions for disposal and other handling

None stated.

7. Manufacturer and Marketing authorization holder

CTS Chemical Industries Ltd.
3 Hakidma st., Kiryat-Malachi
Israel

8. Marketing authorisation number

162-43-35149-00

This leaflet was revised in 12/2022 according to the Ministry of Health guidelines.