PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Minerali oral solution

Each 1 mL contains:
Glucose Monohydrate 14.85 mg
Sodium Chloride 2.70 mg
Potassium Chloride 1.50 mg
Sodium Citrate 2.20 mg

For inactive ingredients in the preparation see section 6 - "Additional information" and the section "Important information about some ingredients of the medicine".

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine.
If you have additional questions, refer to the doctor or the pharmacist.
Take the product according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you have further questions.
Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 24-48 hours.

1. What is the medicine intended for?
Minerali is intended for the prevention of dehydration by replacing fluids and electrolytes loss associated with conditions such as acute diarrhea.
Minerali contains glucose and various salts that belong to a group of medicines called oral electrolyte solutions, which are used to restore fluids and salts lost from the body.
Therapeutic class: Oral electrolytes.

2. Before using the medicine:
☒ **Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You have peripheral and pulmonary edema (swellings) or pre-eclampsia.
- You have glucose malabsorption/intolerance.
- You have very serious vomiting, diarrhea and dehydration which require treatment with fluids.
- You have or have had in the past congestive heart failure or kidney problems or diseases.

Special warnings regarding the use of the medicine:
☒ **Before treatment with Minerali, inform the doctor if:**

- You are suffering from liver problems.
- You are suffering from kidney problems, including oliguria (decreased urine output) or anuria (no urine output).
- You have diabetes.
- You are on a low salt (sodium) diet (see "Important information about some ingredients of the medicine").
- You are on a low potassium diet (see "Important information about some ingredients of the medicine").

If signs of the ailment (symptoms) worsen or do not improve after 24-48 hours, you should refer to the doctor or pharmacist, as another type of treatment may be needed. Treatment of serious and prolonged diarrhea or vomiting should be given only under medical supervision.

☒ **Children and adolescents:**
Minerali may be used in infants above the age of one year.
Minerali should not be given to children under the age of one year without a doctor's recommendation.
If the diarrhea and/or vomiting are serious, refer to a doctor as soon as possible.

☒ **Drug interactions:**
If you are taking or have recently taken other medicines including non-prescription medicines, nutritional supplements, vitamins and herbal supplements, tell the doctor or the pharmacist.
Treatment with Minerali is not expected to affect other medicines you are taking.

☒ **Pregnancy, breastfeeding and fertility:**
Minerali may be used when you are pregnant or breastfeeding.

☒ **Important information about some ingredients of the medicine**
Every 100 mL of Minerali contain 1.35 grams glucose. If you were told by a doctor that you are suffering from sensitivity to certain sugars, you should consult a doctor before taking the medicine.
Every 100 mL of Minerali contain 5 mg of sodium benozate. Sodium benzoate may aggravate jaundice in neonates (up to four weeks of age).
Every 100 mL of Minerali contain 160 mg of sodium, which are equivalent to 8% of the maximal daily intake recommended for an adult.
Every 100 mL of Minerali contain 79 mg of potassium. This amount should be taken into account in patients with reduced kidney function or in patients with a potassium-limited diet.

3. How should you use the medicine?
Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The generally accepted dosage is:
Please note that the solution should be administered in small sips over short intervals. Another sip every few minutes.
During the initial 2-4 hours, administer as follows:
Fluid loss without signs of dehydration (patient is alert, drinking normally, eyes not sunken, tears are produced when crying, normal or slightly decreased urine output, warm fingers and toes, moist lips and tongue, upon pinching the skin on the stomach the skin returns to its place normally): 10 mL/kg after each diarrheic stool and 2 mL/kg after each vomiting.
If the child's weight is unknown:
Under 10 kg (under two years of age) - 50-100 mL after each diarrheic stool or vomiting.
Above 10 kg (from two to 10 years of age) - 100-200 mL after each diarrheic stool or vomiting.
Drinking should be encouraged as much as the patient is willing to drink until the diarrhea passes.
Mild-moderate fluid loss (patient is restless or tired, thirsty, eyes slightly sunken [in babies - the depression in the skull (fontanel) is slightly sunken], decreased tearing while crying, decreased urine output, cold fingers and toes, sticky or dry lips and tongue, upon pinching the skin on the stomach the skin returns to its place slowly): 50-100 mL/kg.
And in addition, 10 mL/kg body weight should be added after each diarrheic stool and 2 mL/kg body weight after each vomiting.
If the child's weight is unknown:
Under 10 kg (under two years of age) - 50-100 mL should be added after each diarrheic stool or vomiting.
Above 10 kg (from two to 10 years of age) - 100-200 mL should be added after each diarrheic stool or vomiting.
Severe fluid loss or a severe disease (bloody diarrhea, diarrhea for more than 48 hours, over 5 times of vomiting in 24 hours, fever above 39°C, patient is drowsy, limp, drinking little or unable to drink, eyes significantly sunken [in babies - the depression in the skull (fontanel) is significantly sunken], lack of tears, dry lips and tongue, decreased urine output, cold fingers and toes): contact the doctor.
About four hours after starting the treatment, its success should be evaluated as well as the improvement in fluid loss. If symptoms of fluid loss still exist, the treatment may be repeated until the symptoms disappear. If the symptoms worsen, contact the doctor.
Breastfed babies and/or babies that receive milk substitute: It is recommended to continue with regular feeding (breastfeeding or milk substitute) during the treatment. Minerali oral solution should be administered according to the recommended dosage and the regular diet should be continued after the first administration of Minerali oral solution or within 4-6 hours.
The solution is ready for drinking and is balanced. Do not add water or sugar, and do not mix the solution with other drinks.
It may be stored in the refrigerator if the child prefers cold drinks.
Drinking the solution may cause slight regurgitation or vomiting. Slight vomiting does not prevent the option of treatment with the solution.
If the baby regurgitates or vomits - try to give him the solution slowly using a spoon or in very small sips in order to improve absorption.
If you accidentally take a higher dosage:
If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:
As with any medicine, using Minerali may cause side effects in some users. However, using Minerali is not expected to cause any side effects.
If a side effect occurs, or if one of the side effects worsens, consult with the doctor.
Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- To be used up to 3 days from the day of opening.

6. Additional information:
In addition to the active ingredients, the medicine also contains:
Purified water, Phosphoric acid Diluted 10%, Hydrochloric acid 10%, Cherry flavour, Citric acid anhydrous, Sorbic acid, Sodium cyclamate, Saccharin sodium, Sodium benzoate
What does the medicine look like and what are the contents of the package: a bottle with a child-safety cap containing 500 mL of clear, colorless to yellowish solution with a cherry scent.
Name and address of the manufacturer and marketing authorization holder: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.
The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in 07/2019 and has been updated in accordance with the Ministry of Health guidelines in 11/2020.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 162-43-35149-00

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