

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed without a doctor's prescription.

BISMU-CAL Tablets

Active ingredient and its amount:

Each tablet contains:

Bismuth subsalicylate 262.5 mg

Inactive ingredients and allergens in the medicine – see section 6 "additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. The medicine is intended for adults and children above 12 years of age. Children below 12 years of age, you should refer to a doctor. Take the medicine according to the instructions in the dosage section in this leaflet (section 3 - How should you use the medicine). Consult the pharmacist if you need further information. Stop taking the medicine and refer to the doctor if signs of illness (symptoms) worsen or do not improve after two days. Furthermore, the treatment should be discontinued, and you should refer to the doctor immediately if the diarrhea is accompanied by high fever, or if you experience ringing in the ears or loss of hearing.

1. What is the medicine intended for?

- Relief of diarrhea, nausea, flatulence, convulsive stomach pains, upset stomach.
- As a preventative treatment of traveler's diarrhea.

Therapeutic group: Intestinal adsorbents.

2. Before using the medicine:

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients the medicine contains (see section 6 – Additional information).
- Do not use for illnesses accompanied by fever, such as flu and chickenpox (for fear of Reye's syndrome).
- The medicine contains salicylate. Do not use the medicine if you are allergic to salicylates (including aspirin) or if you are taking other preparations that contain salicylate.
- You are suffering from a stomach ulcer, bleeding, bloody or black stool.

Special warnings regarding the use of the medicine:

Before the treatment with Bismu-Cal tell the doctor if:

- You are pregnant or breastfeeding.
- You are suffering, or have suffered in the past, from impaired function of the respiratory system (e.g. asthma), the kidney/urinary tract, the digestive system (e.g., stomach ulcer), the blood system (e.g. coagulation, etc.), gout, dehydration, or if you have a fever.
- You are sensitive to any type of food or medicine, in particular to aspirin and salicylates, inform the doctor before taking the medicine.
- Do not use this medicine for children and adolescents under 20 years of age suffering from flu or chickenpox, or if they have a fever or have lost large amounts of fluids.
- Do not give to children or adults for the treatment of nausea on an organic background.
- Do not use the medicine if the signs of illness (symptoms) worsen or do not improve after two days.

- Do not use this medicine frequently or for a prolonged period without consulting the doctor.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Aspirin and salicylates
- Anticoagulants
- Medicines for gout, probenecid or sulfapyrazone
- Tetracyclines
- Medicines for diabetes
- Medicines for arthritis

Use of the medicine and food:

The Medicine can be taken with or without food.

Use of the medicine and alcohol consumption:

Do not drink wines or alcoholic beverages during treatment with the medicine.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, consult a doctor before using the medicine.

Important information about some of the ingredients of the medicine:

This medicine contains less than 1 mmol sodium (23 mg) per tablet (each tablet contains 2.74 mg sodium) that is to say essentially "sodium-free".

3. How should you use the medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The generally accepted dosage is:

Adults and children above 12 years of age: 2 tablets.

For children below 12 years of age: consult a doctor.

If recommended by the doctor - children below 9 years of age: It is recommended to use a liquid form medicine prescribed by the doctor, which contains the active ingredient bismuth subsalicylate.

This dosage can be repeated, if necessary, every half hour to an hour, up to 8 times in a 24-hour period.

Do not exceed the recommended dose.

Method of administration

Swallow the medicine with water.

Do not split Bismu-Cal tablets.

To make swallowing easier, if necessary, the tablet may be crushed or chewed and immediately swallowed with water. The crushed or chewed tablet may have a bitter taste.

If you have accidentally taken a higher dosage:

If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by the doctor.

If you forgot to take the medicine: If you forgot to take this medicine at the required time, take a dose as soon as you remember, but never take two doses together!

How can you contribute to the success of the treatment?

In case of diarrhea, drink plenty of caffeine-free fluids in order to make up for the loss of fluids.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Bismu-Cal may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop using this medicine and refer to a doctor immediately if:

The following symptoms occur:

- Weakness
- Convulsions
- Breathing problems
- Blurred vision
- Confusion
- Ringing in the ears or loss of hearing
- Severe constipation.

Stop using and refer to the doctor as soon as possible if:

Signs of overdose occur, such as drowsiness and headache.

In case of diarrhea accompanied by high fever.

This medicine may cause a change in the color of your stool or tongue. These changes are not a cause for concern.

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking the link "report side effects of Drug Treatment" that can be found on the homepage of the Ministry of Health website (www.health.gov.il) directing to an online form for reporting side effects, or by clicking the link: <https://sideeffects.health.gov.il>.

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor. Do not use the medicine after the expiry date (exp. Date) stated on the package. The expiry date refers to the last day of that month.

Storage conditions: Store in the original package at a temperature below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Calcium Carbonate, Microcrystalline Cellulose, Sodium Starch Glycolate (type A), Povidone k 30, Magnesium Stearate, Colloidal Anhydrous Silica.

What does the medicine look like and what the package contains?

White or almost white tablet, round, biconvex, with special embossing "two points with quarter circle" on one side and plain on the other side.

The tablets are packaged in blisters, in a box containing 21 tablets (3 blisters of 7 tablets).

Name and address of the Marketing

Authorization Holder and Importer:

RAZ pharmaceuticals LTD., 31 GESHER HAETZ ST., INDUSTRIAL PARK, EMEK HEFER, ISRAEL.

Drug registration number at the national drug registry of the Ministry of Health:

176-35-38028-99.

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