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

The medicine is dispensed without a doctor's prescription

BISMURAZ Tablets

Active Ingredient:
Each tablet contains:
Bismuth subsalicylate 262.5 mg

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

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, consult the doctor or pharmacist. 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.

1. What is the medicine intended for?

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

Therapeutic group: Adsorbents of fluids and toxins from the intestine and stools.

Bismuraz contains the active ingredient bismuth subsalicylate. It works by creating a soothing and protective coating of the stomach and intestine.

2. Before using the medicine:

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, or to salicylates, including aspirin or to any of the other ingredients the medicine contains (see section 6 – Additional information).
- You are taking other salicylates, including aspirin.
- You are pregnant or breastfeeding.

Special warnings regarding the use of the medicine:
Before starting the treatment with Bismuraz tell the doctor if:

- You suffer from a blood clotting disorder or gout.

Stop using the medicine and refer to a doctor if:

- The diarrhea is accompanied by fever.
- You suffer from ringing in the ears.
- You notice anything unusual or have unexpected side effects.

If you suffer from diarrhea, it is important to prevent dehydration or treat it by drinking plenty of fluid or taking oral rehydration products, especially if you are frail or elderly.

Children and adolescents
The medicine is intended for adults and children over the age of 12.
Under the age of 12, consult a doctor. This medicine is not intended for use in children and adolescents who have or have recovered from chicken pox or flu-like symptoms. See section 4 - "Side effects".

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
- Blood thinning medicines (Anticoagulants).
- Medicines to treat diabetes.
- Medicines to treat gout.
- Antibiotic medicines from the Tetracycline group.

Use of the medicine and food:
The Medicine can be taken with or without food.

Pregnancy and breastfeeding:
Do not use the medicine during pregnancy or while breastfeeding.

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 of 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 under 12 years of age: consult a doctor.
If recommended by the doctor - children under 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 Bismuraz 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 dose:
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.

Symptoms of overdose:
Bismuth intoxication
May present as acute encephalopathy with confusion, myoclonic movements, tremor, dysarthria and walking and standing disorders. Bismuth intoxication may also cause gastrointestinal disturbances, skin reactions, discolouration of mucous membranes, and renal dysfunction as a result of acute tubular necrosis.

Salicylate poisoning
Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

Respiratory alkalosis combined with metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is common effect in adults and children over the age of 4 years. In children aged 4 years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.

Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopaenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.
Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

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

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 Bismuraz 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.

Children and adolescents:
If there are behavioral changes, including nausea and vomiting, while taking this medicine, consult the doctor, since these symptoms may be an early sign of Reye's syndrome, a rare but serious disease.

Additional side effects
This medicine may cause a temporary and harmless change in the colour of your stools or tongue (a darker colour). If these symptoms do not pass within 3 days of stopping using this medicine - **consult your doctor or pharmacist**.

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 the 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 due to 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 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 are the contents of the package?
White or almost white tablet, round, biconvex, with embossing of "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 pharmaceutics LTD.,
31 GESHER HAETZ ST., INDUSTRIAL PARK,
EMEK HEFER, ISRAEL.

Drug registration number at the national drug registry of the Ministry of Health:
174-23-36492-99.

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