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

This medicine is dispensed without a doctor's prescription

Bitni tablets 262 mg

Each tablet contains:
Bismuth Subsalicylate 262 mg

Bitni Suspension 17.5 mg/ml

Each dose of 15 ml contains:
Bismuth Subsalicylate 262 mg

For inactive ingredients and allergens, see section 2, subsection "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 other questions, refer to the doctor or the pharmacist.

Take the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need further information. Refer to the doctor if the symptoms of the ailment worsen or do not improve after two days.

1. What is the medicine intended for?

- For relief in cases of diarrhea, nausea, flatulence, abdominal cramps, upset stomach and indigestion.
- For prevention of traveler's diarrhea.

Therapeutic class: absorbent of fluids and toxins from the intestines and the stool.

The preparation contains the active ingredient bismuth subsalicylate, which works by forming a soothing and protective coat in the stomach and intestines.

2. Before using the medicine:

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, to salicylates, including aspirin, or to any of the additional components the medicine contains.
- You are taking other salicylates, including aspirin.
- You are pregnant or breastfeeding.

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

- You suffer from a blood clotting disorder or from gout.

Stop using this medicine and refer to a doctor if:

- The diarrhea is accompanied by fever
- You suffer from ringing in the ears
- You notice an abnormal effect or suffer from unexpected side effects

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

Children and adolescents:
The medicine is intended for adults and children above 12 years of age. Below the age of 12 years, you should refer to a doctor.

The preparation is not intended for use in children and adolescents who are suffering or recovering from chickenpox or from 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 the pharmacist. Especially if you are taking:

- Aspirin and salicylates
- Blood thinning medicines (anticoagulants)
- Medicines for treatment of diabetes
- Medicines for treatment of gout
- Tetracycline antibiotics

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

Pregnancy, breastfeeding and fertility:
Do not use this medicine during pregnancy or breastfeeding.

Important information about some of the ingredients of the medicine:
Bitni tablets:
The medicine contains less than 23 mg of sodium per dose (2 tablets), and is therefore considered sodium-free.
Bitni Suspension:
The medicine contains less than 23 mg of sodium per 30 ml dose, and is therefore considered sodium-free.
The medicine contains 240 mg of propylene glycol per 30 ml dose.
The medicine contains 39 mg of sodium benzoate per 30 ml dose.
The medicine contains Ponceau 4R which may cause allergic reactions.

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:

Bitni tablets:
Adults and children over the age of 12 years: 2 tablets.
Children below 12 years of age: consult a doctor.
If recommended by the doctor – children under 9 years of age: it is recommended to use **Bitni Suspension**.
This dosage can be repeated as necessary every half hour to an hour, up to 8 times in any 24-hour period.
Swallow the medicine with water.
Crushing/halving/chewing:
The tablet should not be halved in order to take a reduced dose.
Do not chew. The tablet is intended to be swallowed. However, to help swallowing, the tablet may be crushed/halved as necessary, and then used immediately. All parts should be swallowed immediately after crushing/halving.

Bitni Suspension:
Adults and children over the age of 12 years: 30 ml.
Children below 12 years of age: consult a doctor.
This dosage can be repeated every half hour to an hour, up to 8 times in any 24-hour period.
Shake well before use, then drink according to the recommended dosage.
Be sure to measure the dose using the enclosed measuring cup.

Do not exceed the recommended dose.
If you accidentally took a higher dosage:
If you took an overdose or if a child accidentally swallowed this medicine, refer to the doctor or to a hospital emergency room immediately and take the package of the medicine with you. Do not induce vomiting without an explicit instruction from the doctor.

Symptoms of overdose:

- Bismuth poisoning:
  May appear as an acute encephalopathy with confusion, myoclonic movements, tremor, speech disorder and gait and standing disorders.
  In addition, bismuth poisoning may cause digestive system disturbances, skin reactions, change in the color of the mucous membranes and impaired kidney function as a result of acute tubular necrosis.
- Salicylate poisoning:
  The common characteristics include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm limbs with a pounding pulse sensation, increased breathing rate and hyperventilation. In most cases there is a certain degree of acid-base balance disorder.
  Respiratory alkalosis in combination with metabolic acidosis, with a normal or high arterial pH (normal or reduced concentration of hydrogen ions) is a common effect in adults and children above the age of 4 years. In children aged 4 years and below, metabolic acidosis with low arterial pH (increased concentration of hydrogen ions) is common. Acidosis may increase the passage of salicylate through the blood-brain barrier.
  Uncommon characteristics include bloody vomit, high fever, hypoglycemia, hypokalemia, thrombocytopenia, increased INR/PTR, intravascular coagulation, renal failure and noncardiogenic pulmonary edema.
  Central nervous system characteristics, 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 this medicine at the appointed time, take your dose as soon as you remember. However, under no circumstances should you take two doses together.

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

4. Side effects:

As with any medicine, using the preparation 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.

In children and adolescents: if, while using this preparation, behavioral changes occur together with nausea and vomiting, consult a 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 color of the stool or tongue (a darker color). If these symptoms do not resolve after 3 days of discontinuing the preparation – **consult the doctor or pharmacist.**

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult 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 via 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 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. date) appearing on the package.
The expiry date refers to the last day of that month.
Storage conditions: store at a temperature below 25°C.
Use after opening Bitni Suspension: can be used for up to two months from opening.

6. Additional information:

In addition to the active ingredient the medicine also contains:
Bitni tablets:
Calcium carbonate, Microcrystalline cellulose, Hydroxypropyl cellulose, Pregelatinized Starch, Sodium Starch Glycolate, Ready to use coating blend Opadry TF 265F240033 PINK (w/w composition: Hypromellose 62.50%, Calcium Carbonate 26.82%, Macrogol 6000 10%, FD&C Red 40 0.68%), Magnesium Stearate.
Bitni Suspension:
Propylene Glycol, Xanthan Gum, Sodium Salicylate, Sucralose, Sodium Benzoate, Strawberry Cream Flavor, Salicylic Acid, Ponceau 4R, Purified Water.

What does the medicine look like and what are the contents of the package?
Bitni tablets:
A package containing 2, 7, 10, 15, 20, 30, 50 or 60 pink, round, biconvex, film-coated tablets.
Not all package sizes may be marketed.
Bitni Suspension:
A bottle containing 100 ml of pink suspension with an aroma of strawberries.

Name and address of the manufacturer and license holder: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.

This leaflet was revised in 09/2025 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:

- Bitni tablets – 140-65-31601-00
- Bitni Suspension – 140-75-31557-00

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