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

This medicine is dispensed without a doctor's prescription

Bitni X tablets 262 mg

Each tablet contains:
Bismuth Subsalicylate 262 mg
For details regarding additional ingredients of the medicine, see 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.
The medicine is intended for adults and children above 12 years of age. Below the age of 12, you should refer to a doctor.
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 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 in cases of diarrhea, nausea, flatulence, abdominal cramps, upset stomach and indigestion.
Prevention of traveler's diarrhea.

2. Before using the medicine:

X Do not use this medicine if:

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

Special warnings regarding the use of the medicine:
! Before starting treatment with **Bitni X** inform 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.

! Do not use this medicine for children and adolescents under 20 years of age suffering from the flu or chickenpox, or if they have a fever or have lost large amounts of fluids.
! Do not give to children or adults for treatment of nausea on an organic background.
! Do not use this medicine if signs of the illness (symptoms) worsen or do not improve after two days.
! Do not use this medicine frequently or for a prolonged period of time without consulting the doctor.
! Drug-drug interactions:
If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially inform the doctor or pharmacist if you are taking:

- Aspirin and salicylates
- Medicines against blood clotting
- Medicines for gout, such as probenecid or sulfinpyrazone
- Tetracyclines
- Medicines for diabetes
- Medicines for arthritis

! Use of the medicine and food:
The medicine may be taken with or without food.
! Use of the medicine and alcohol consumption:
Do not drink wine or alcoholic beverages during treatment with this medicine.
! Pregnancy, breastfeeding and fertility:
If you are pregnant or breastfeeding, consult a doctor before using the medicine.
! Important information about some ingredients of the medicine:
This medicine contains less than 23 mg of sodium per dose (2 tablets), and is therefore considered sodium-free.
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:
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 liquid **Bitni X**.
This dosage can be repeated as necessary every half hour to an hour, up to 8 times in any 24-hour period.
Do not exceed the recommended dose.
Method of administration
The medicine should be taken with water.
Crushing/halving/chewing:
Do not chew. The tablet is intended to be swallowed.
The tablet should not be halved in order to take a reduced dose.
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.
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 induce vomiting without an explicit instruction from the doctor.
If you forgot to take the medicine: If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.
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 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 **Bitni X** 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 use and refer to the doctor as soon as possible if:
Signs of overdose occur, such as drowsiness, headache, and 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 occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, 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 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.
Storage: Store at a temperature lower than 25°C.

6. Additional information:

In addition to the active ingredient the medicine also contains:
Calcium carbonate, Povidone K-25, Pregelatinized Starch, Sodium Starch Glycolate, Hypromellose 4910, Magnesium Stearate, Ponceau 4R, Macrogol 6000.
What does the medicine look like and what are the contents of the package:
A package containing 2, 7, 10, 15, 20, 30, 50, 60 pink, round, biconvex, coated tablets.
Not all package sizes may be marketed.
Name and address of the Manufacturer and Marketing Authorization Holder: CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi.
This leaflet from 03/2020 is formatted according to the requirements of the Ministry of Health, and its content matches the leaflet of the original preparation, which was checked and approved by the Ministry of Health in 01/2015.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1406531601.

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