

**PATIENT LEAFLET AS PER THE  
PHARMACISTS' REGULATIONS  
(PREPARATIONS) 1986**

The drug is marketed without doctor's prescription

**Bitni X tablets**

**Each tablet contains:  
Bismuth Subsalicylate 262 mg**

For the list of additional ingredients contained in the medicine, see section 6 - Additional information

**Read the entire leaflet carefully before you start using the medicine.** This leaflet contains essential information about the medicine. If you have any further questions, contact your doctor or the pharmacist.

The medicine is intended for adults and children above the age of 12 years. Below the age of 12 years, contact a doctor.

You must use the medicine appropriately. Consult a pharmacist if you need more information. You must contact your doctor if symptoms worsen or do not improve after 2 days. Stop the treatment and contact a doctor immediately if you experience high fever, tinnitus or hearing loss.

**1. What is the medicine intended for?**

The medicine is intended for the relief of diarrhea, nausea, gas, spasmodic abdominal pain, indigestion and dyspepsia. For prevention of travelers' diarrhea.

**2. Before using the medicine:**

**✗ Do not use the medicine if:**

- Hypersensitivity (allergy) to any of the medicine ingredients or to salicylates is known.
- You are taking another salicylate containing medicine, including Aspirin.
- You are below the age of 20 and suffer from diseases associated with fever, such as flu and chickenpox (in view of the concern of Reye syndrome).
- You suffer from gastric ulcer, bleeding, bloody or black stool.

**Special warnings regarding the use of this medicine:**

■ Prior to commencing treatment, consult a doctor if you suffer or have previously suffered from impaired function of the: respiratory system (such as asthma), renal/urinary system,

gastrointestinal system (such as gastric ulcer), hematological system (such as coagulation etc.), gout, diabetes, dehydration (dry mouth, thirst, dizziness), fever, mucus in stool.

■ Do not use this medicine frequently or for prolonged period of time without consulting a doctor.

■ If you are sensitive to any food or medicine, you must notify your doctor prior to taking this medicine.

■ Do not give to children or adolescents for treatment of nausea caused by a structural defect in the gastrointestinal system.

■ Do not use the medicine if symptoms worsen or do not improve after 2 days.

■ If while taking this medicine, you experience changes in behavior, accompanied by vomiting and nausea, consult your doctor since these symptoms may be the first signs of Reye's syndrome (a rare but serious disease)

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. In particular, inform your doctor or pharmacist if you are taking:**

- Aspirin and salicylates
- anticoagulants
- anti-diabetic medication
- anti-gout medication such as Probenecid or Sulfinpyrazone
- Tetracyclines (antibiotics)
- Arthritis medication

**Use of this medicine and food:**

You may take the medicine with or without food.

**Use of the medicine and alcohol consumption:**

Do not drink wine or alcoholic beverages during treatment.

**Pregnancy and lactation:**

If you are pregnant or breastfeeding, consult a doctor prior to using this medicine.

**Important information about some of the medicine ingredients:**

Each tablet contains 1.14 mg of sodium.

**3. How should you use the medicine?**

You should check with your doctor or the pharmacist if you are unsure.

The standard dosage is usually:

Adults and children above the age of 12: 2 tablets  
The dose may be repeated every 30 minutes to one hour as required, up to the maximum

of 8 doses per 24 hours

Children under 12 years: consult a doctor. If your condition has not improved within 2 days, or if the diarrhea is accompanied by a high fever, contact a doctor.

Do not exceed the recommended dose

**Do not chew! Swallow the medicine with water; if required, you may crush the tablet and swallow it immediately.**

If you took an overdose or by mistake a child swallowed this medicine, go to the emergency room of the hospital immediately and take the package of the medicine with you.

If you have forgotten to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

How can you assist in treatment success? In case of diarrhea, drink plenty of caffeine-free beverages to overcome 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 any further questions regarding the use of this medicine, contact your doctor or pharmacist.

**4. Side Effects:**

As with any medicine, use of Bitni X may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

**Stop the treatment and contact a doctor immediately if the following symptoms appear:**

Weakness, convulsions, respiratory problems, blurred vision, confusion, tinnitus or hearing loss, severe constipation.

**Stop the treatment and contact a doctor as soon as possible if:**

- you experience symptoms of overdose, such as somnolence, headache.
- in case of diarrhea accompanied by fever. This medicine may alter the color of the stool or tongue; these changes should not cause any concern.

**Additional side effects:** Constipation, diarrhea, nausea.

If any side effect worsens, or if you suffer from a side effect not mentioned in the leaflet, you should consult your doctor.

**5. How should the medicine be stored?**

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from your doctor.

Do not use the medicine after the expiration date (exp. date) that appears on the package. The expiration date refers to the last day of that month.

Store at a temperature below 25°C.

Store in the original packaging.

**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 pack containing 2, 7, 10, 15, 20, 30, 50, 60 pink, round and biconvex tablets.

Not all pack 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 was checked and approved by the Ministry of Health on: 1/2015

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1406531601



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