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

The medicine is dispensed with a doctor's prescription only

ATZIRUT X Enteric Coated Tablets 5 mg

Each tablet contains: Bisacodyl 5 mg
For information regarding inactive ingredients and allergens, see section 2 - "Important information about some 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.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

The medicine is intended for relief of constipation in adults and children above 6 years of age, in ambulatory or bedridden patients, and is given as preparation for certain tests.
Therapeutic class: a laxative that contains a colon stimulant (contact laxative).

2. Before using the medicine:

☒ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient bisacodyl or to any of the additional ingredients the medicine contains (see section 6 "Additional information").
- You have intolerance (sensitivity) to certain sugars or you cannot digest certain sugars (as the tablet contains a small amount of lactose).
- You are severely dehydrated.
- You have a bowel problem called ileus (bowel obstruction).
- You have a severe abdominal problem such as appendicitis.
- You have severe abdominal pain accompanied by nausea and vomiting.
- You have a bowel obstruction or chronic bowel dysfunction.
- You have an inflammation of the bowels (the small intestine or the colon).

❗ Special warnings regarding the use of the medicine:

- Prolonged use may lead to dependence on laxative preparations (such as this one), as well as diarrhea. Do not use this medicine frequently or for a prolonged period of time without consulting the doctor.
- This medicine is intended only for treatment of constipation lasting a few days, since prolonged use of the medicine may cause the bowels to become dependent on laxatives for bowel movement. Bowel inactivity for a day or two does not justify using this medicine.
- **Atzirut X** should not be used for other purposes, such as "body cleansing" etc.

Is this medicine effective for weight loss?
Laxatives (such as bisacodyl) are inefficient for weight loss. They do not reduce absorption of calories or food. They can cause watery stools (diarrhea), abdominal pain and dehydration. Dehydration can be mistaken for weight loss. Overuse of laxatives may damage your health in the following ways:

- Causing disturbances in electrolytes and minerals balance. Sodium, potassium, magnesium and phosphorus are electrolytes and minerals that are required in very accurate concentrations for proper functioning of nerves and muscles, including colon and cardiac muscles. Disturbing this delicate balance may lead to impaired function of these vital organs.
- Severe dehydration may cause tremors, weakness, blurry vision, fainting, kidney damage, and in extreme cases, death. Dehydration often requires medical attention.
- Overuse of laxatives should be avoided so as to not damage the functioning of the bowel.

❗ Before starting treatment with Atzirut X, inform your doctor if:

- You are suffering or have suffered in the past from rectal bleeding.
- You have severe abdominal pain.

❗ Children and adolescents:
This medicine is not intended for use in children under 6 years of age.
❗ Drug interactions:
If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist. Especially if you are taking:

- Diuretics, such as bendrofluazide and furosemide.
- Steroidal medicines such as prednisolone.
- Other laxatives.
- Do not take medicines for reduction of gastric acid levels (of the proton pump inhibitors group) or antacids for up to one hour before or after taking this medicine.

After taking this medicine, wait at least two hours before taking other oral medicines, since **Atzirut X** may affect their absorption.
❗ Use of the medicine and food:
Do not consume milk for up to one hour before or after taking **Atzirut X**, as this will prevent the medicine from working properly.
❗ Pregnancy, breastfeeding and fertility:
If you are pregnant, planning to become pregnant, or breastfeeding, consult the doctor before taking **Atzirut X**.
❗ Driving and operating machinery:
Some patients may feel dizziness or fainting while taking this medicine. If you feel these effects, you should wait for them to resolve before driving or operating machinery.
❗ Important information about some ingredients of the medicine:
Atzirut X contains lactose. If you have been told by the doctor that you have an intolerance (sensitivity) to certain sugars, consult the treating doctor before taking this medicine.
This medicine contains less than 23 mg of sodium per tablet, and is therefore considered sodium-free.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined by the doctor only.
The generally accepted dosage is:
Adult dosage: 1-3 tablets in the evening before bedtime.
If this is the first time you are taking this medicine, start with one tablet and increase the dosage as necessary.
Do not take more than 3 tablets per day.
Dosage for children above 6 years of age: one tablet in the evening before bedtime.
Do not exceed the recommended dose.
Duration of treatment:
As with other laxative preparations, do not take **Atzirut X** for more than 5 consecutive days.
If you need to take laxatives every day or if you have a persistent abdominal pain, you should talk to your doctor to find the reason for constipation. Overuse may be detrimental.
How to use the medicine:

- The tablet should be swallowed whole with some water.
- The tablet should not be chewed or crushed, and should not be halved to avoid damaging the function of the tablet's coating.
- Keep yourself hydrated during the day to help soften the stool and prevent dehydration.

The preparation induces bowel activity (usually within 6-12 hours), but sometimes a longer period of time is required (up to 24 hours).
If you accidentally took a higher dosage:
If you have taken too many **Atzirut X** tablets or if you have been taking **Atzirut X** tablets for a prolonged period of time, it may be harmful for you and the following symptoms may occur:

- Fluid and electrolyte imbalance in the body, which may affect muscle tone (for example, in the intestines) and blood electrolytes.
- Low potassium blood levels (called hypokalemia), which may cause muscle weakness and irregular heartbeat.
- Dehydration, which may manifest as a sensation of thirst, fainting, headaches and low urine output.

If you took an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or the emergency room of the hospital and take the package of the medicine with you.
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.
Follow the treatment as recommended by the doctor.
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 **Atzirut 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:
A severe allergic reaction occurs, which includes swelling of the face or throat and breathing difficulties or dizziness (rare).
Common side effects - side effects that occur in 1-10 out of 100 users:

- Abdominal spasms or pain
- Diarrhea
- Nausea

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:

- Blood in the stool
- Vomiting
- Abdominal discomfort
- Anal and perianal discomfort
- Dizziness
- This medicine may cause urine discoloration. Do not worry about this change

Rare side effects - side effects that occur in 1-10 out of 10,000 users:

- Colitis (an inflammation of the colon, which causes abdominal pain and diarrhea)
- Dehydration
- An allergic reaction which may cause a rash
- Fainting

If one of the side effects worsens, or if you suffer from a side effect not indicated 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 and sight 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.
- Store at a temperature lower than 25°C.
- Do not discard medicines via wastewater or the trash. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. Additional information:

In addition to the active ingredient the medicine also contains:
Lactose monohydrate, Microcrystalline cellulose, Pregelatinised starch, ACRYL-EZE 93A240007 Pink ready-to-use powder mix (Methacrylic acid and Ethyl acrylate copolymer, Talc, Titanium dioxide, Colloidal anhydrous silica, Sodium bicarbonate, Sodium lauryl sulfate, Red iron oxide, Yellow iron oxide), Triethyl citrate, Magnesium stearate.
What does the medicine look like and what are the contents of the package?
The package contains 1, 3 or 5 blister trays, each containing 10 tablets. The tablets are pink, oval and coated, and are debossed on one side with 'CTS'.
Not all package sizes may be marketed.
Manufacturer/license holder and address:
CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.

This leaflet was revised in 11/2023 in accordance with the Ministry of Health guidelines.
Registration number of the medicine in the national drug registry of the Ministry of Health: 130-99-30854-00

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