

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

This medicine is dispensed without a doctor's prescription

Name of the preparation and its form:

**Tzarevet X Mint Flavour chewable tablets
Tzarevet X Melon Flavour chewable tablets**

Each tablet contains: calcium carbonate 500 mg (elemental calcium 200 mg)
Acid-neutralizing capacity per tablet: 10 mEq.
For a list of inactive ingredients and allergens in the preparation, please see section 6 – "Additional information" and the section "Important information about some of the ingredients of the medicine".

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 product according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 14 days.

Do not take Tzarevet X concomitantly with other medicines as specified in section 2 "Drug interactions".

1. What is the medicine intended for?

For relief of heartburn and stomach acidity.

Therapeutic class: antacids.

2. Before using the medicine:

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient calcium carbonate or to any of the other ingredients the medicine contains (listed in section 6).
- You have excess of calcium in the blood (hypercalcemia) or excess of calcium in the urine (hypercalciuria).
- You are on a low phosphate diet.
- You suffer from parathyroid problems.
- You suffer from impaired renal function.
- You suffer from Zollinger-Ellison syndrome.
- You are taking a cardiac glycoside (for example: digoxin).

Children and adolescents

This medicine should not be used in children under 12 years of age.

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:

- Thiazide diuretics.
 - Bisphosphonates for treatment of bone loss.
 - Tetracyclines and ciprofloxacin (antibiotics).
- It is recommended to wait 2-3 hours between taking this medicine and taking other oral medicines.

Pregnancy, breastfeeding and fertility:

No risks have been observed in pregnant or breastfeeding women taking calcium carbonate at the recommended doses.
If you are pregnant, planning to become pregnant or breastfeeding, consult the doctor or pharmacist before using the medicine. See section 3 – "How should you use the medicine?"

Driving and operating machinery

Calcium carbonate has no known effects on the ability to drive and operate machinery.

Important information about some of the ingredients of the medicine:

Each tablet of Tzarevet X Mint Flavour chewable tablets contains about 7 mg of aspartame.

Each tablet of Tzarevet X Melon Flavour chewable tablets contains about 4.5 mg of aspartame.

Aspartame is a source for phenylalanine, which may be harmful if you have phenylketonuria (PKU), a rare genetic disorder that causes the accumulation of a large amount of phenylalanine in the body because the body cannot eliminate it properly.

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 for adults and children above 12 years of age is:

Chew 2-4 tablets when symptoms appear, or according to the doctor's recommendation. Do not take more than 15 tablets in 24 hours. If you are pregnant, do not take more than 9 tablets in 24 hours.

Do not exceed the recommended dose.

Duration of treatment – do not use the maximum dose for more than two weeks, except on the recommendation and under the supervision of your doctor.

Do not use this medicine if the symptoms continue for more than 2 weeks, except on the recommendation of your doctor.

Crushing/halving/chewing

The tablet may be crushed/chewed.

If you took an overdose

If you accidentally took a higher dose or if a child accidentally swallowed the medicine, immediately refer to a doctor or to a hospital emergency room and bring the package of the medicine with you.

Symptoms of an overdose may include: anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, tiredness, mental disorders, excessive thirst, excessive urination, bone pain, kidney calcification, renal calculi and in severe cases disturbances in heart rhythm. Extreme overdose of calcium may cause coma and death.

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult a 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 Tzarevet X tablets 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. Constipation, flatulence, nausea, burping may occasionally appear.

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 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.

Storage conditions: store in the original packaging in a dry place, at a temperature lower than 25°C.

6. Additional information:

In addition to the active ingredient, the medicine also contains:

Tzarevet X Mint Flavour:

Mannitol, Povidone (K-25), Sodium starch glycolate, Magnesium stearate, Aspartame, Peppermint flavour

Tzarevet X Melon Flavour:

Mannitol, Povidone (K-25), Sodium starch glycolate, Magnesium stearate, Melangor flavour, Aspartame, Quinoline Yellow E104, FD&C Blue NO.1 Lake

What does the medicine look like and what are the contents of the package?

Tzarevet X Mint Flavour:

Each chewable tablet is white, round with a depression and has a characteristic mint odor.

Tzarevet X Melon Flavour:

Each chewable tablet is yellow-green, round with a depression and has a characteristic melon odor.

The package contains 1, 2, 3, 6, 12, 18, 24, 36 chewable tablets in a blister pack.

Not all package sizes may be marketed.

Manufacturer/marketing authorization holder and address:

CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.

This leaflet was revised in 08/2024 in accordance with the Ministry of Health guidelines.

Registration numbers of the medicines in the national drug registry of the Ministry of Health:

Tzarevet X Mint Flavour registration number:

1311430847

Tzarevet X Melon Flavour registration number:

1311730850

