

Do not take Tzarevet X concomitantly with other medicines as specified in section 2 "Drug-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).
- In patients with excess of calcium in the blood (hypercalcemia) or excess of calcium in the urine (hypercalciuria).
- In patients on low phosphate diet.
- In patients with parathyroid problems.
- In patients with kidney problems (e.g., kidney stones).
- In patients with Zollinger-Ellison syndrome.
- In patients receiving digoxin for treatment of a cardiac disease.

### **❗ Drug-drug interactions:**

**If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell the doctor or the pharmacist.** Especially inform the doctor or pharmacist if you are taking:

Thiazide diuretics, bisphosphonates for treatment of bone loss, tetracyclines and ciprofloxacin (antibiotics).

After taking this medicine, wait 2-3 hours before taking other oral medicines.

### **❗ Pregnancy, breastfeeding and fertility:**

If you are pregnant or breastfeeding, you should consult the doctor or pharmacist before using the medicine. See section 3 - "The accepted dosage".

### **❗ Important information about some 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.

**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 10 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.

The medicine is not intended for children under the age of 12.

**Form of administration** - chew or dissolve in the mouth.

### **Crushing/halving/chewing**

The tablet may be pulverized/chewed.

**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.

**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. These side effects include: constipation, flatulence, nausea, burping.

**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 your 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](http://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 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/license holder and address:**

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

This leaflet from 01/2021 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 12/2014.

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

## **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)

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 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.

Tzarevet X is intended for children above 12 years of age.

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 ailment (symptoms) worsen or do not improve after two weeks.



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