PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed without a doctor's prescription.

N-ZAREVET
Chewable fruit-flavored tablets

Each tablet contains Calcium Carbonate 500 mg.

Inactive ingredients: see section 6 in the leaflet.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine does not require a doctor's prescription. Use it properly. The medicine is intended for children above 12 years of age. Refer to the doctor if the symptoms worsen or if they do not improve after two weeks. Consult the pharmacist if you need further information.

1. WHAT IS THE MEDICINE INTENDED FOR?

Antacid.

2. BEFORE USING THE MEDICINE

X Do not use the medicine if:

- You have had a sensitivity (an allergy) to calcium carbonate or to any of the other ingredients in this medicine (see section 6 in the leaflet).
- You suffer from 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 kidney stones.
- You suffer from impaired function of the parathyroid glands.
- You suffer from Zollinger-Ellison Syndrome.
- You are being treated with digoxin for a heart disease.
- There are signs of appendicitis or intestinal inflammation, such as: abdominal pain, nausea or vomiting.
- Do not use the medicine in children under 12 years of age.

! Before treatment with N-Zarevet, consult the doctor if:

- You are pregnant or breastfeeding.
- You suffer from diabetes (the preparation contains sugar).
- You suffer or have suffered in the past, from impaired function of the digestive system, from liver diseases, heart/vascular diseases, bone fractures.

! Additional warnings:

Do not use if the inner seal under the cap is missing or damaged.

! Use in children:

- This medicine is not intended for infants and children under 12 years of age.

! Use of N-Zarevet with food:

If you are sensitive to any food or medicine, inform the doctor before taking the medicine. The preparation contains sugar (dextrose) and therefore, if you suffer from intolerance to certain sugars, consult the doctor before taking the medicine.

! If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist before commencing treatment, especially with regard to medicines from the following groups:

Tetracyclines, ciprofloxacin (fluoroquinolones) (antibiotics), thiazide-type diuretics, corticosteroids, vitamin D, bisphosphonates, digitalis, methenamine, sodium polystyrene, sulfonate, phenytoin, medicines which contain: iron, calcium, phosphate, magnesium, fluoride, antifungals (ketoconazole).

Allow a lapse of 2-3 hours between taking this medicine and taking other oral medicines.

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

The orange tablet contains FD&C Yellow #6 Aluminium Lake, which may cause allergic reactions.

3. HOW SHOULD YOU USE THE MEDICINE?

- Check with the doctor or pharmacist if you are unsure.
- This medicine is not intended for infants and children under 12 years of age.

The usual dosage, unless otherwise instructed by a doctor, is generally:

For relief of heartburn: chew 2-4 tablets upon the onset of symptoms or as per the doctor's recommendation.

If there is no improvement in the heartburn within two weeks, refer to the doctor. Do not use the medicine for more than two weeks, except at the recommendation and supervision of the doctor. Do not exceed the recommended dose of 15 tablets per day.

If you are pregnant, do not take more than 10 tablets in 24 hours.

Directions for use:

Chew the medicine before swallowing.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of N-Zarevet 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
- Nausea
- Flatulence
- Belching

If a side effect occurs, if any of the side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the online form for reporting side effects that can be found on the Ministry of Health homepage www.health.gov.il or via the following link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- 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. date) that is imprinted on the bottle. The expiry date refers to the last day of that month.
- Do not store different medicines in the same package.
- Store in the original package.
- Store below 25°C.
- Can be used for 12 months after first opening.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Red tablet:

Dextrose, Maltodextrin, Polyethylene glycol, Talc, Adipic acid, Powdered cellulose, Art cherry flavor, Mineral oil, Nat cream flavor, FD&C RED #40 Aluminium Lake.

Green tablet:

Dextrose, Maltodextrin, Polyethylene glycol, Talc, Adipic acid, Powdered cellulose, Nat lime flavor, Mineral oil, FD&C yellow #5 Aluminium lake, FD&C Blue #1 Aluminium Lake.

Orange tablet:

Dextrose, Maltodextrin, Polyethylene glycol, Talc, Adipic acid, Powdered cellulose, Nat&Art orange flavor, Mineral oil, FD&C Yellow #6 Aluminium Lake.

Yellow tablet:

Dextrose, Maltodextrin, Polyethylene glycol, Talc, Adipic acid, Powdered cellulose, Nat&Art lemon flavor, Mineral oil, FD&C Yellow #5 Aluminium Lake.

The preparation contains sugar! Each tablet contains about 510 mg dextrose. Each tablet also contains between 0.226-0.392 mg sodium (depending on the color of the tablet).

What the medicine looks like and the contents of the package:

The tablets are packed in a bottle which contains 150 tablets. The tablets are round and imprinted with "L478" on one side.

- Registration holder and address: Perrigo Israel Agencies Ltd., 29 Lehi Street, Bnei-Brak, 51200.
- Manufacturer and address: Perrigo Co., Michigan, U.S.A.
- This leaflet was checked and approved by the Ministry of Health in December 2015.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 13845.31624