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

The medicine is dispensed without a doctor's prescription

TUMS ULTRA ASSORTED BERRIES, CHEWABLE TABLETS 1000 mg

Each tablet contains calcium carbonate 1000 mg (elemental calcium 400 mg)
Acid-neutralizing capacity per tablet: 20 mEq.
Inactive and allergenic ingredients in the preparation – please see section 6.

Read the 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.
Take the preparation in accordance with the instructions in section 3 "How should you use the medicine?" of this leaflet. Consult a pharmacist if you need further information. Refer to a doctor if the symptoms worsen or are not improving after 14 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

For relief of heartburn and stomach acidity.

Therapeutic group: Antacids.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to calcium carbonate or to any of the additional ingredients contained in the medicine (listed in section 6)
- You have excess calcium in the blood (hypercalcemia) or excess calcium in the urine (hypercalciuria)
- You are on a low-phosphate diet
- In patients with parathyroid gland function problems
- You have impaired kidney function
- In patients with Zollinger-Ellison syndrome
- You are taking a cardiac glycoside (e.g., digoxin)

Children and adolescents:
Do not use the medicine 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 pharmacist. Especially if you are taking:

- Thiazide diuretics
- Bisphosphonates for treatment of bone thinning

- Tetracyclines and ciprofloxacin (antibiotics).

It is recommended to wait between 2 and 3 hours between taking this medicine and taking other oral medicines.

Pregnancy, breastfeeding and fertility

No risks were observed in pregnant or breastfeeding women who took calcium carbonate at the recommended dosages.

If you are pregnant, planning to become pregnant or are breastfeeding, consult the doctor or pharmacist before using the medicine.

See section 3 – "How should you use the medicine"?

Driving and operating machinery

No effects of calcium carbonate on the ability to drive and operate machinery have been observed.

Important information about some of the ingredients of the medicine

- The medicine contains sugars. If you have been told by your doctor that you have an intolerance to certain sugars, refer to your doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage generally recommended for adults and children over 12 years of age is: chew 2 to 3 tablets when symptoms appear, or as per the doctor's recommendations. Do not take more than 7 tablets within 24 hours.

If you are pregnant, do not take more than 5 tablets within 24 hours. Do not use the maximal dose for more than two weeks, unless recommended and monitored by the doctor. Do not use the medicine if the symptoms persist for more than two weeks, unless recommended by the doctor. **Do not exceed the recommended dosage.**

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

Symptoms of overdose may include: anorexia, thirst, nausea, vomiting, constipation, abdominal pains, muscle weakness, fatigue, mental disturbances, excessive thirst, excessive urination, bone pain, calcification in the kidneys, kidney stone and in severe cases, heart rate disturbances. Extreme calcium overdose may cause coma and death.

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

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

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

4. SIDE EFFECTS

As with any medicine, use of Tums Ultra may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
Constipation, flatulence, nausea and belching may rarely occur.

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

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store below 25°C.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Sucrose, Corn starch, Talc, Mineral oil, Adipic acid, Sodium hexametaphosphate, Natural and artificial flavors, FD&C Red, FD&C Blue
- What the medicine looks like and the contents of the package:
  A plastic bottle that contains 160 or 265 chewable tablets. The bottle is closed with an inner seal and cover. In addition, it is available in a roll package of 12 tablets.

Not all package sizes may be marketed.

- License holder: GSK Consumer Healthcare Israel Ltd., P.O.B. 3256, Petach Tikva.
- Manufacturer: GSK Consumer Healthcare Holdings, St. Louis, USA.
- This leaflet was revised in December 2021 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 124-55-30280-00

TumUlt PT v6