SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

TUMS SMOOTHIES EX BERRY FUSION

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Calcium Carbonate 750 mg per tablet.

3 PHARMACEUTICAL FORM

Chewable Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of heartburn.

4.2 Posology and method of administration

The usual dosage for adults and children over the age of 12 is generally: chew 2 to 4 tablets when symptoms occur, or as recommended by the physician. Maximal daily dose is 10 tablets.

For pregnant, maximal daily dose is 6 tablets in 24 hours. Do not use the maximum dose for more than two weeks except under the advice and supervision of your physician. Do not use the medicine if the symptoms persist for more than two weeks, unless recommended by the physician. Do not exceed the recommended dose.

If you accidentally took a higher dosage, or if a child has accidentally swallowed the medicine, refer immediately to a physician 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, tiredness, mental disturbances, excessive thirst, excessive urination, bone pain, renal calcification, nephrolithiasis and, in severe cases, heart rate disturbances. Extreme overdose of calcium may cause coma and death.

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

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Contraindicated in patients with hypercalcaemia, hypercalciuria, or on a low-phosphate diet. Or those receiving cardiac glycosides or with impaired renal function.

Contraindicated in patient with thyroid dysfunction, Zollinger-Ellison syndrome.

4.4 Special warnings and precautions for use

Prolonged use of higher than recommended doses may result in hypercalcaemia and milk alkali syndrome, particularly in patients with renal insufficiency.

As an ingredient of flavour, this medicine contains:

- Sulphur dioxide . May rarely cause severe hypersensitivity reactions and bronchospasm
- Benzyl alcohol. This is because large amounts of benzyl alcohol can build-up in the body and may cause side effects (called “metabolic acidosis”).
- Sorbitol. Sorbitol is a source of fructose.
- Propylene Glycol alginate.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids of this type are known to decrease the absorption of concomitantly administered drugs, such as bisphosphonates, tetracyclines and ciprofloxacin due to adsorption or delaying of gastric emptying or alkalinisation of gastric juice. This can be avoided by giving other drugs 2-3 hours before or after the administration of calcium carbonate on the advice of a doctor. However, the activity of cardiac glycosides such as digoxin may be increased due to the presence of elevated calcium concentrations.

The risk of hypercalcaemia should be considered in patients taking thiazide diuretics since these drugs can reduce urinary calcium excretion.

4.6 Fertility, pregnancy and lactation

Pregnancy

Data on a large number of exposed pregnancies indicate no adverse effects of TUMS SMOOTHIES EX BERRY FUSION on pregnancy or on the health of the fetus/newborn child. To date, no other relevant epidemiological data are available.

Breast Feeding

TUMS SMOOTHIES EX BERRY FUSION are unlikely to present a risk to breastfeeding women at recommended doses.

The MDD as an antacid in pregnancy is 4.5g calcium carbonate.

Calcium carbonate is unlikely to present a risk to pregnant or breastfeeding women at recommended doses.

If you are pregnant do not take more than 6 tablets per day.

4.7 Effects on ability to drive and use machines

Calcium carbonate is unlikely to cause any effects on the ability to drive and use machines.

4.8 Undesirable effects

Constipation, flatulence, nausea and belching are likely to occur rarely.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il/
Additionally, please also report to GSK Israel (il.safety@gsk.com)

4.9 Overdose

Overdose of calcium can lead to hypercalcaemia. Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, nephrolithiasis and in severe cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death.

Treatment: withdrawal of the product and normal laxative measures. Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Calcium carbonate is an antacid.

5.2 Pharmacokinetic properties

Not applicable, since calcium carbonate acts locally in the gastrointestinal tract.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium Carbonate Granulated 95% w/w containing Calcium Carbonate and Gum Acacia, Dextrose, Sorbitol Powder, Microcrystalline Cellulose and Guar Gum, Calcium Stearate, Adipic Acid.

In addition:

Orange Passion Fruit tablet: N&A Orange Passion Fruit, Purple Powder Blend

Cherry tablet: Entrapped N&A Cherry Type Flavour, Cherry Powder Blend

Strawberry tablet: Strawberry Flavor, Strawberry Flavour Blend

Citrus Berry tablet: Red Powder Blend, N&A Citrus Berry Twist

6.2 Incompatibilities

None.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials

6.4 Special precautions for storage

Store below 25°C.
Keep out of the sight and reach of children.

6.5 Nature and contents of container

Polypropylene bottle containing either 12, 60 or 72 tablets.

Not all package sizes may be marketed.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

GSK Consumer Healthcare, Israel Ltd.
P.O.B 3256, Petach Tikva, 4951038, Israel

8 MANUFACTURER

Glaxosmithkline Consumer Healthcare Holdings (US) LLC, USA
320 South Broadway, Saint Louis MO 63102, USA

9 MARKETING AUTHORISATION NUMBER

143-86-32015-00

The content of this leaflet was revised in October 2020.