

MAALOX TC

A02AD01

magnesium hydroxide and dried aluminum hydroxide gel Suspension Chewable tablets

COMPOSITION

100 ml of suspension contain:

Active ingredients:

Magnesium hydroxide 6.00 g

Dried aluminum hydroxide gel 12.00 g

Excipients:

Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Guar gum, Sorbitol solution 70%, Citric acid, Peppermint oil essence, Purified water.

Each tablet contains:

Active ingredients:

Magnesium hydroxide 300 mg

Dried aluminum hydroxide gel 600 mg

Excipients:

Mannitol, Granular mannitol, Saccharose, Sorbitol solution 70%, Glycerin, Paraffin liquid, Swiss cream flavor, Peppermint essence, Lemon flavor, Magnesium stearate, Talc.

PHARMACEUTICAL FORMS AND PRESENTATIONS

Suspension for oral use

- Box with 15 sachets of 15 ml suspension.

- Bottle of 200 ml suspension.

Tablets for oral use

- Box with 40 chewable tablets.

PHARMACOTHERAPEUTIC CATEGORY

Maalox TC is a formulation having a high concentration of magnesium and aluminum hydroxides with a high antacid and antiulcer activity.

HOLDER OF THE MARKETING AUTHORISATION

AVENTIS PHARMA S.p.A.

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MANUFACTURER

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INDICATIONS

For the prevention of stress-induced hemorrhages of the gastroduodenal tract. As antacid in the symptomatic therapy of pyrosis and epigastric pain related to peptic ulcer or to another gastrointestinal pathology, where a high neutralizing capacity is required.

CONTRAINDICATIONS

In states of renal failure, use the drug only under the physician monitoring.

PRECAUTIONS

Never take more than 3 tablespoonfuls/3 sachets (45 ml) of suspension or 9 tablets in the 24-h period, never go over this dosage for longer than 2 weeks and use the product in case of kidney disease only after having consulted your doctor.

INTERACTIONS

The administration of Maalox TC could reduce the absorption of some antibiotics of the family of tetracyclines or of other drugs (phenytoin, digoxin, indomethacin, furosemide, isoniazide, anticholinergic agents). Therefore, it is preferable to keep an interval of 2 hours between the administration of Maalox TC and the above mentioned drugs.

USE DURING PREGNANCY AND LACTATION

Though no adverse reactions are known, during pregnancy and lactation it is advisable, as with any drug, to limit the use to the medical prescription.

WARNINGS

Keep out of the reach of children.

DOSE, MODE AND TIME OF ADMINISTRATION

- Prevention of stress-induced hemorrhages of the upper gastroenteric tract

Estimate the pH value of gastric aspirate, then introduce with the aid of a nasogastric probe 10 ml of Maalox TC suspension along with 30 ml of water. Check every hour, by suction, if the gastric content is at pH ≥ 4 . If it is lower, introduce a double Maalox TC suspension with 30 ml of water until assuring a pH value ≥ 4 .

- Symptomatic therapy

15 ml, one tablespoonful or one sachet of suspension or 3 tablets well chewed or sucked, one hour after meals and before bed resting or depending on the physician's evaluation.

Higher dosage schedules may be employed, under the direct medical control, in the treatment of peptic ulcer.

Shake thoroughly the suspension before the use

Tablets should be well chewed or sucked.

OVERDOSAGE

In case of accidental overdosage, consult the physician for the suitable therapies.

ADVERSE EFFECTS

Maalox TC, for its composition, has no tendency to modify the pattern of the bowel. However, in a few subjects and at high doses, an acceleration of the intestinal transit could occur. Occasionally, a regurgitation could occur at the doses recommended for the prevention of stress-induced hemorrhages of the gastro-duodenal tract.

In case of onset of adverse effects differing from those described above, inform your attending physician.

ATTENTION: Never use the product after the expiry date printed on the outer label.

SPECIAL PRECAUTIONS FOR THE STORAGE

Suspension: store above 4 degrees

Bottle: keep the bottle well stoppered

Tablets: store below 30 degrees

DATE OF THE LAST REVISION: July 2001