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

The medicine is dispensed without a doctor's prescription

Name of the preparation and its form:

Maalox Plus Chewable Tablets

SANOFI

Active ingredients and their quantity per dosage unit:

Each tablet contains:

Aluminium Oxide hydrated 200 mg
Magnesium hydroxide 200 mg
Dimethicone 25 mg

Inactive ingredients: see section 6.

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.
Keep this leaflet; you may need to read it again.
Use according to the instructions in the Dosage section in this leaflet. Consult the pharmacist if you need further information.
Refer to the doctor if symptoms worsen or are not improving.
The medicine is not intended for children.

1. WHAT IS THE MEDICINE INTENDED FOR?

Maalox Plus contains three different medicines: two that belong to the group called antacids and one which is an anti-foaming agent.
Maalox Plus is used as an antacid, anti-flatulence agent and to relieve the sensation of heartburn in the digestive system.
Therapeutic group: antacid and anti-flatulence agent in the digestive system.

2. BEFORE USING THE MEDICINE

Do not use the medicine if you:

- are sensitive (allergic) to aluminium hydroxide, magnesium hydroxide, simethicone or to any of the other ingredients (see section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- feel severe exhaustion.
- are suffering from kidney problems.
- are suffering from severe abdominal pain or partial or full bowel obstruction.
- are suffering from a low blood phosphate level. This condition can be identified in your blood tests.

Do not take the medicine if one of the conditions listed above applies to you. If you are uncertain, talk to your doctor or pharmacist before using the medicine.

Special warnings regarding use of this medicine:
Refer to the doctor or pharmacist before beginning treatment if you are on a low-phosphorus diet.

Children and adolescents
Maalox Plus Chewable Tablets is not intended for children.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Do not take Maalox Plus and other medicines at the same time, since Maalox Plus may affect the activity of other medicines.
If Maalox Plus is taken within one hour of another medicine, it may affect the absorption of the medicine into the blood.
Some medicines may be affected by magnesium hydroxide or may affect the activity of magnesium hydroxide.
Wait at least two hours between taking other medicines and taking Maalox Plus (a lapse of 4 hours for fluoroquinolone).

Tell the doctor or pharmacist if you are taking:
salicylates

In particular, inform the doctor or pharmacist if you are taking:

- preparations to treat infections, such as: tetracycline, rifampicin, ketoconazole, penicillamine, or lincosamide antibiotics, e.g., clindamycin or fluoroquinolone antibiotics (e.g., ciprofloxacin, ofloxacin, levofloxacin), or antibiotics for treating tuberculosis – ethambutol, isoniazid, or cephalosporin antibiotics (e.g., cefdinir, cefpodoxime)
- H_2 antagonists used for treatment of gastric ulcer, e.g., cimetidine, ranitidine, famotidine
- bisphosphonates used for the treatment of osteoporosis or Paget's disease, e.g., alendronate sodium, etidronate sodium, risedronate sodium
- glucocorticoids
- neuroleptics of the phenothiazine group, e.g., fluphenazine, thioridazine
- preparations containing iron salts
- propranolol, metoprolol, atenolol, digoxin (preparations given for cardiac diseases/blood pressure)
- preparations to treat malaria, e.g., chloroquine, hydroxychloroquine
- chlorpromazine (antipsychotic)
- diflunisal, indomethacin (analgesics)
- sodium fluoride (preparation for prevention of dental caries)
- levothyroxine (for treatment of thyroid gland hormone deficiency)
- rosuvastatin (for lowering blood cholesterol levels)
- vitamins
- polystyrene sulfonate (kayexalate – preparation for treatment of potassium excess)
- combined administration with quinidine can cause an increase in blood quinidine levels
- combined administration with preparations containing citrate can increase aluminium levels, particularly in patients suffering from kidney function problems

Use of the medicine and food
Chew the tablet 20 minutes to one hour after meals and at bedtime.

Pregnancy and breastfeeding
Consult the doctor or pharmacist before using this medicine if:

- you are pregnant, may become pregnant, or think you are pregnant. Do not use the medicine during the first three months of pregnancy.
- you are breastfeeding or plan to breastfeed.

Important information about some of the ingredients in this medicine
The tablet contains glucose (500.5 mg), sucrose and sorbitol (50 mg per tablet).
If the doctor told you that you suffer from a problem of intolerance or from a disturbance in digestion of certain sugars, or if you have been diagnosed as suffering from hereditary fructose intolerance (HFI), a rare genetic disorder, in which people suffering from it cannot break down fructose, consult the doctor before using the medicine.

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The medicine may be harmful to the teeth.
For patients with diabetes, the amount of glucose should be taken into consideration.

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.

Intended for administration by mouth. The tablets should be **thoroughly chewed** before swallowing them.

The usual dosage is generally:

The usual dosage for adults and the elderly:

One or two tablets, 4 times a day, 20 minutes to one hour after meals and at bedtime, or according to doctor's instructions.

Do not exceed the recommended dosage.

If the symptoms do not pass, refer to the doctor. Do not take for more than two weeks without instruction from the doctor.

Maalox Plus Chewable Tablets is not intended for children.

Tests and follow-up

If you have to have diagnostic tests with radioactive reagents, inform the doctor that you are taking this medicine, as the test results may be affected by the presence of aluminium.

If you accidentally took an overdose 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. In such a case, you may suffer from diarrhea, abdominal pain, bloating, vomiting, indigestion, heartburn, upset stomach, constipation, loss of appetite, dry mouth. These can be caused by intestinal obstruction.

High dosages of the preparation may cause or worsen phosphate deficiency, bone problems, increased calcium levels in the urine, rickets.

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 the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Maalox Plus may cause side effects in some users. Do not be alarmed by the list of side effects; you may not suffer from any of them.

Stop taking the medicine and refer immediately to the doctor or proceed to a hospital emergency room if:

Side effects of unknown frequency (cannot be evaluated from the existing data):

You suffer from a red and lumpy skin rash, swollen eyelids, face, lips, mouth or tongue, itching, difficulty breathing or swallowing.

This could be an allergic reaction.

Consult the doctor if a side effect occurs, if one of the following side effects worsens or lasts longer than a few days, or if a side effect that was not mentioned in this leaflet occurs:

Uncommon side effects (may occur in up to 1 patient in 100):

- Constipation
- Diarrhea

Very rare side effects (may occur in up to 1 patient in 10,000):

- Hypermagnesemia (excessive magnesium in the blood), including observations after prolonged administration to patients with renal impairment

Side effects of unknown frequency (cannot be evaluated from the existing data):

- Hypophosphatemia (decrease in blood phosphate level) that may occur with a high dosage of the preparation, and even at normal doses especially in patients with low phosphorus diets
- Hyperaluminemia (condition of abnormally high blood aluminium level)
- Abdominal pain

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 a 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

Do not store at a temperature exceeding 25°C. Store in the original package to protect from moisture.

Do not dispose of medicines in the household waste bin or wastewater. Ask your pharmacist how to dispose of medicines you no longer need. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Glucose anhydrous- 500.50 mg/tab, Maize starch, Mannitol- 75 mg/tab, Sucrose- 75mg/tab, Sorbitol liquid non-crystallizing- 32.80mg/tab (corresponding to 22.96 mg of Sorbitol), Sorbitol - 22.04 mg/tab, Talc, Magnesium stearate, Pregelatinized starch (Maize starch), Lemon flavor, Citric acid anhydrous, Saccharine sodium 1.5mg/tab, Swiss cream flavor, Iron oxide yellow (E-172).

What the medicine looks like and contents of the package

Maalox Plus Tablets are white-yellowish, lemon-flavored and -scented tablets, with the name "Maalox" emossed on one side.

Quantity per package: 40 or 50 tablets per package. Not all package sizes may be marketed.

This leaflet does not contain all the information about the preparation. If you have any questions or are not sure about something, please refer to the doctor.

License holder and address: sanofi-aventis Israel ltd., P.O.B. 8090, Netanya.

Manufacturer and address: Sanofi S.p.A, Scoppito, Italy.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1076620355