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 Suspension

SANOFI

Active ingredients and their quantity per dosage unit:
Each teaspoon (5 ml) contains:
Aluminium hydroxide 175 mg
Magnesium hydroxide 200 mg

Inactive ingredients – see section 6 and "Important information about some of the ingredients in this medicine" section.

Read this leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or pharmacist.
Keep this leaflet; you may need to read it again.
Take this preparation according to the instructions in the Dosage section in this leaflet or according to the doctor's instructions. Consult the pharmacist if you need further information. Refer to the doctor if symptoms worsen or are not improving.
If one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, refer to the doctor or pharmacist.
The medicine is not intended for children under 14 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Maalox Suspension contains two different medicines that belong to the group called antacids.
The preparation is intended to reduce the amount of gastric acid and to relieve the sensation of heartburn.
Therapeutic group: antacids.

2. BEFORE USING THE MEDICINE

☒ Do not use the medicine if:
- you are allergic to aluminium hydroxide or magnesium hydroxide or to any of the other ingredients of the medicine (see section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- you feel severe exhaustion.
- you are suffering from kidney problems. Prolonged exposure to high doses of Maalox Suspension may lead to dementia.
- you are suffering from severe abdominal pain.
- you are suffering from partial or full bowel obstruction.

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
This medicine is not intended for children under 14 years of age.

! Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.
Do not take Maalox Suspension and other medicines at the same time, since Maalox Suspension can affect the activity of other medicines.
Wait at least two hours between taking them and taking Maalox Suspension (a lapse of 4 hours for fluoroquinolone).
Some medicines may be affected by magnesium hydroxide or may affect the activity of magnesium hydroxide.

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 (e.g., ethambutol, isoniazid), or cephalosporin antibiotics (e.g., cefdinir, cefpodoxime).
- H2 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 for the treatment of cardiac disease/blood pressure)
- preparations to treat malaria, e.g., chloroquine, hydroxychloroquine
- diflunisal, indomethacin (analgesics)
- chlorpromazine (antipsychotic)
- 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 dysfunction

! Use of the medicine and food
The medicine can be taken with water or milk.
Drink the suspension 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
Maalox Suspension contains sorbitol. The medicine contains 50 mg sorbitol per 5 ml dose. Sorbitol is a source of fructose. 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 disease, in which people suffering from it cannot breakdown fructose, consult the doctor before using the medicine.
Maalox Suspension contains less than 1 mmol sodium (23 mg) per 5 ml dose i.e. essentially 'sodium free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.
Shake well before use; intended for administration by mouth. If necessary, the medicine can be taken with water or milk.
The usual dosage for adults, the elderly, and children above 14 years of age:
10-20 ml, 20 minutes to one hour after meals and at bedtime or according to doctor's instructions.
You must use a measuring spoon or cup intended for measuring the correct amount of medicine. Do not use a household spoon to measure the amount of medicine. Household spoons differ in size and you may not get the correct amount of medicine.
Do not exceed the recommended dosage.
If the symptoms do not pass, refer to the doctor.
This medicine is not intended for children under 14 years of age.
Do not take for more than two weeks without instruction from the doctor.

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 have accidentally taken 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 all medicines, use of Maalox Suspension 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.

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

Side effects of unknown frequency (frequency cannot be evaluated from the existing data)
- Hypophosphatemia – abnormal decrease in blood phosphate level that may occur with prolonged use or a high dosage of the preparation, and even at normal doses, especially in patients with low phosphorous diets
- Abdominal pain
- Hyperaluminemia – abnormal increase in blood aluminium level

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

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 of the preparation. The expiry date refers to the last day of that month.

Storage conditions:
Store at a temperature below 25°C.
Do not freeze. Keep the bottle tightly closed.
After first opening, can be used for 6 months.
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:
Sorbitol liquid 70% (non crystallizing) 71.45 mg/5 ml, Hydrochloric acid 10%, Mannitol, Citric acid monohydrate, Hydrogen peroxide solution 30%, Saccharin sodium 1.4 mg/5 ml, Peppermint oil, Domiphen bromide 0.211 mg/5 ml, Purified water.

What the medicine looks like and contents of the package
Maalox Suspension is white, mint-flavored and scented, packaged in a white 250 ml or 355 ml bottle. 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 anything, 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, Origgio, Italy.
Revised in September 2020 according to MOHs guidelines.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 485924105.