PACKAGE LEAFLET: INFORMATION FOR THE USER

Maalox® Plus

200mg/200mg/25mg Chewable Tablets

hydrated aluminium oxide 200mg
magnesium hydroxide 200mg
dimeticone (as simeticone) 25mg

SANOFI

Read all of this leaflet carefully because it contains important information for you
This medicine is available without prescription. However, you still need to use Maalox Plus Chewable Tablets carefully to get the best results from it.
- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact a doctor if your symptoms worsen or do not improve
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Maalox Plus Chewable Tablets are and what they are used for

Maalox Plus Chewable Tablets contain three different medicines:
- The first two medicines are called hydrated aluminium oxide, and magnesium hydroxide. They belong to a group of medicines called antacids.
- The other medicine is called dimeticone (as simeticone). It belongs to a group of medicines called antifoaming agents.

Maalox Plus Chewable Tablets are used for:
- The relief of indigestion (dyspepsia)
- Heartburn
- Wind (flatulence)

Maalox Plus Chewable Tablets work by lowering the amount of acid in your stomach. The anti-foaming agent in Maalox Plus Chewable Tablets helps to remove gas from your stomach.

2. What you need to know before you take Maalox Plus Chewable Tablets

Do not take Maalox Plus Chewable Tablets if:
- You are allergic (hypersensitive) to hydrated aluminium oxide, magnesium hydroxide, dimeticone (as simeticone) or any of the other ingredients in Maalox Plus Chewable Tablets (see Section 6: Further information). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You are feeling very weak and have no energy (debilitated)
- You have kidney problems
- You have low levels of phosphate (called "hypophosphataemia"). This is shown up in blood tests

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Maalox Plus Chewable Tablets.

Warnings and precautions
Take special care with Maalox Plus Chewable Tablets

Check with your doctor or pharmacist before taking your medicine if:
- You suffer from porphyria
- You suffer from diabetes

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Maalox Plus Chewable Tablets.

Other medicines and Maalox
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines.
Maalox Plus Chewable Tablets should not be taken at the same time as other medicines. This is because Maalox Plus Chewable Tablets can affect the way other medicines work.
Talk to your doctor or pharmacist before taking Maalox Plus Chewable Tablets if you are taking aspirin or drugs containing acetylsalicyclic acid.

Other medicines and magnesium hydroxide:
Some medicines may be affected by magnesium hydroxide or they may affect how well magnesium hydroxide will work. Tell your doctor or pharmacist if you are already taking: - salicylates

In particular, Maalox Plus Chewable Tablets can affect the following medicines:
- Medicines used to treat the heart such as digoxin, quinidine, metoprolol, atenolol or propranolol.
- Medicines used to treat anaemia such as iron salts.
- Medicines used to treat stomach ulcers and acidity such as ranitidine or cimetidine (H2 antagonists).
- Medicines used to treat malaria such as chloroquine.
- Medicines used to treat some bone disorders such as bisphosphonates.
- Medicines used to treat some allergic, inflammatory or abnormal immune reactions such as glucocorticoids.
- Medicines used to treat kidney disorders such as citrates.
- Medicines used to treat tuberculosis such as ethambutol or isoniazid.
- Medicines used to treat infections such as fluoroquinolones, lincosamides, ketoconazole, cyclines, cephalosporins, (cefpodoxime & cefdinir), dolutegravir, elvitegravir, raltegravir potassium and antiviral treatment combination of tenofovir alafenamide fumarate/emtricitabine/bictegravir sodium, rilpivirine.
- Medicines used to treat mental illness (psychosis) such as phenothiazines, neuroleptics.
- Medicines used to treat increased amounts of potassium in the body such as polystyrene sulfonate.
- Medicines used to treat pain such as diflunisal, indomethacin
- Medicines used in dental care such as sodium fluorure
- Medicines used to treat an underactive thyroid gland such as levothyroxine
- Medicines used to treat joint pains and abnormal chemical reactions in the body such as penicillamine
- Medicines used to reduce cholesterol such as rosuvastatin
- Medicines used to treat cancer such as nilotinib, dasatinib monohydrate
- Medicines used to treat blood disorders such as eltrombopag olamine
- Medicines used to treat high blood pressure in the lungs (pulmonary hypertension) such as riociguat

As a precaution, staggering the administration times of any orally administered drugs and the antacid by at least 2 hours (4 hours for the fluoroquinolones).

Pregnancy and breast-feeding
Use of Maalox Plus Chewable Tablets is not recommended during pregnancy.

Talk to your doctor about using Maalox Plus Chewable Tablets if:
- You are pregnant or planning to become pregnant
- You are breast-feeding or planning to breast feed

Important information about some of the ingredients of Maalox Plus Chewable Tablets
Maalox Plus Chewable Tablets contain glucose, sucrose and sorbitol (E420). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.
Care should be observed if used by diabetics because of the sugar content in the tablet.
Maalox Plus Chewable Tablets also contain sulphur dioxide (E220), which may rarely cause hypersensitivity reactions and bronchospasm.
Maalox Plus Chewable Tablets contain small amounts of ethanol (alcohol), less than 100mg per dose.

Maalox plus Chewable Tablets contain sodium
This medicine contains less than 1 mmol sodium (23 mg) per chewable tablet, this is to say essentially "sodium-free".

3.How to take Maalox Plus Chewable Tablets

Taking this medicine
- Take this medicine by mouth
- Chew the tablets well before swallowing

Adults
- Take one or two tablets 4 times each day
- Take 20 minutes to one hour after meals and at bedtime or as required

Do not take this medicine for prolonged periods as it may mask more serious diseases such as stomach ulcers or stomach cancer.

If the symptoms do not go away, talk to your doctor.

Children
Not recommended in children.

If you take more Maalox Plus Chewable Tablets than you should
The following effects may happen: diarrhoea, stomach pain or you may get a bloated feeling and cramping pain in the abdomen (stomach), be sick (vomit), have indigestion, heartburn, upset stomach, constipation, loss of appetite, dry mouth. This could be caused by an obstruction or blockage of the bowel (ileus).
Talk to your doctor or go to a hospital straight away. Remember to take any medicine that is left with you so the doctor knows what you have taken.

4.Possible side effects

Like all medicines, Maalox Plus Chewable Tablets can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet:
Uncommon:
- Constipation
- Diarrhoea

Very rare:
- Hypermagnesemia, inlcuding observations after prolonged administration of magnesium hydroxide to patients with renal impairment.

Not Known:
- Allergic or anaphylactic reactions, signs include; red and lumpy skin rash, swollen eyelids, face, lips, mouth or tongue, itching, difficulty breathing or swallowing.
- Abdominal pain
- Hypophosphatemia, this may occur at high doses of the product or even at normal doses especially in patients with low phosphorus diets or in infants less than 2 years.
- Hyperaluminemia is an electrolyte disturbance in which there is an abnormally elevated level of aluminium in the body

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
You can report side effects directly via:
In Ireland:
HPRA Pharmacovigilance.
Website: www.hpra.ie
In Malta:
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5.How to store Maalox Plus Chewable Tablets

Keep out of the sight and reach of children.

Do not use Maalox Plus Chewable Tablets after the expiry date which is stated on the carton and foil after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original package in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6.Contents of the pack and other information

What Maalox Plus Chewable Tablets contain
- Each tablet contains: 200mg of hydrated aluminium oxide, 200mg of magnesium hydroxide and 25mg of dimeticone (as simeticone)
- The other ingredients are: sucrose, mannitol, sorbitol liquid non crystallising, sorbitol, saccharin sodium, magnesium stearate, talc, pregelatinised maize starch, maize starch, citric acid anhydrous, glucose anhydrous, lemon flavour (contains sulphur dioxide (E220)), swiss cream flavour (contains sulphur dioxide (E220) and ethanol) and iron oxide yellow (E172).

What Maalox Plus Chewable Tablets looks like and contents of the pack
Maalox Plus Chewable Tablets have a white and yellow layer with "Maalox" embossed on the white side. They taste of lemon/cream.

Maalox Plus Chewable Tablets are made in blister packs containing 10, 12, 20, 24, 30, 36, 40, 48, 50, 60, 70, 80, 84, 90, 96, and 100 tablets. Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
In Ireland:
Opella Healthcare France SAS, T/A Sanofi,
82 Avenue Raspail, 94250 Gentilly, France.
In Malta:
Opella Healthcare France SAS, T/A Sanofi,
82 Avenue Raspail,
94250 Gentilly,
France.

Manufacturer
Sanofi S.r.l
S.S. 17, Km 22, 67019 Scoppito (AQ), Italy

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

For any information about this medicine, please contact the distributor & local representative of the Marketing Authorisation Holder:

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Waterford Road, Clonmel,
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Email: medicalinformation@clonmel-health.ie

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DATE: 03-03-2023
DESCRIPTION: IST MAALOX PLUS 200MG IE I01
PACK. ITEM: Istruzioni
MARKET: IE: IRELAND
COLOURS: ■ Black
CODE SAP/ID N°: 883054
TECHNICAL DRAW. CODE: 62C0018 V.3.0
LAETUS: 010111011001000
REPLACED CODE SAP/ID N°: 874624
DIE CUT:
PHARMACODE : 89487
BLISTER SIZE:
EXT. DIM.: 167x315mm singola
PROOF N°: 1
PACKAGING LINE:
PRODUCT LOGO:
MIN. FONT SIZE: 9 pt su 10 pt
PAGE: 2 / 2
BRAILLE: fustella num.
IMPIANTO DI PROPRIETÁ: Sanofi S.r.l.
Text approval Date: Signature:
Final approval Date: Signature:
1 - Prima realizzazione 2 - Ins. "PH:"
Arkhé S.n.c. Tel. 0862.404140 fax 0862.090006
Verificare la corrispondenza dell'artwork approvato - la nostra responsabilità è limitata al rifacimento dei file forniti.

883054 - IST MAALOX PLUS 200MG IE I01

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