

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Maalox Plus Tablets

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Aluminium hydroxide gel (dried)	200mg
Magnesium hydroxide	200mg
Simeticone	25mg

## **3 PHARMACEUTICAL FORM**

Tablet

Bi-layered white and yellow tablets, 16mm in diameter, with 'Maalox' embossed on one side.

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

The symptomatic relief of:

1. Dyspepsia
2. Heartburn
3. Flatulence

## **4.2 Posology and method of administration**

Route of administration: Oral

Adults (including elderly persons): 1-2 tablets well chewed, four times a day, taken twenty minutes to one hour after meals and at bedtime, or as required.

Children: Not recommended

## **4.3 Contraindications**

Should not be used in patients who are severely debilitated or suffering from kidney failure.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Hypersensitivity to the active ingredients or to any of the excipients.

## **4.4 Special warnings and precautions for use**

Aluminium hydroxide may cause constipation and magnesium salts overdose may cause hypomotility of the bowel; large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at higher risk such as those with renal impairment, or the elderly.

Aluminium hydroxide is not well absorbed from the gastrointestinal tract, and systemic effects are therefore rare in patients with normal renal function. However, excessive doses or long-term use, or even normal doses in patients with low-phosphorus diets, may lead to phosphate depletion (due to aluminium-phosphate binding) accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia. Medical advice is recommended in case of long-term use or in patients at risk of phosphate depletion.

In patients with renal impairment, plasma levels of both aluminium and magnesium increase. In these patients, a long-term exposure to high doses of aluminium and magnesium salts may lead to encephalopathy, dementia, microcytic anaemia, or worsen dialysis-induced osteomalacia,

Aluminium hydroxide may be unsafe in patients with porphyria undergoing haemodialysis. The prolonged use of antacids in patients with renal failure should be avoided.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Maalox Plus should not be taken simultaneously with other medicines as they may interfere with their absorption if taken within 1 hour.

Aluminium-containing antacids may prevent the proper absorption of drugs notably H<sub>2</sub> antagonists, atenolol, bisphosphonates, cefdinir, cefpodoxime, chloroquine, chlorpromazine, ciprofloxacin, cyclines, dasatinib monohydrate, dexamethasone, diflunisal, digoxin, eltrombopag olamine, elvitegravir, ethambutol, fluoroquinolones, glucocorticoids, hydroxychloroquine, indomethacin, iron salts, isoniazid, ketoconazole, levothyroxine, lincosamides, metoprolol, nilotinib, penicillamine, phenothiazine neuroleptics, propranolol, raltegravir potassium, rifampicin, rilpivirine, riociguat, rosuvastatin, sodium fluoride, antiviral treatment combination of tenofovir alafenamide fumarate/emtricitabine/bictegravir sodium, tetracyclines, and vitamins.

With the integrase inhibitors (dolutegravir, raltegravir, bictegravir) the combination should be avoided (please refer to their SmPC for dose recommendations).

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

Levothyroxine may also bind to simeticone which may delay or reduce the absorption of levothyroxine.

##### **Polystyrene sulphonate**

Caution is advised when used concomitantly with polystyrene sulphonate due to the potential risk of reduced effectiveness of the resin in binding potassium of metabolic alkalosis in patients with renal failure (reported with aluminium hydroxide and magnesium hydroxide), and of intestinal obstruction (reported with aluminium hydroxide).

##### **Quinidine:**

Concomitant use of aluminium products with quinidines may increase the serum levels of quinidine and lead to quinidine overdosage.

##### **Tetracycline:**

Because of the aluminium content, Maalox Plus should not be concomitantly administered with tetracycline-containing antibiotics or any tetracycline salts.

##### **Citrates:**

Aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.

Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

#### **4.6 Fertility, Pregnancy and lactation**

The safety of Maalox Plus Tablets in pregnancy has not been established.

##### Pregnancy

There are no available data on Maalox Plus use in pregnant women. No conclusions can be drawn regarding whether or not Maalox Plus is safe for use during pregnancy. Maalox Plus should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the fetus.

##### Lactation

Because of the limited maternal absorption, when used as recommended, minimal amounts, if any, of aluminium hydroxide and magnesium salt combinations are expected to be excreted into breast milk.

Simeticone is not absorbed from the gastrointestinal tract.

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to aluminium hydroxide, magnesium hydroxide and simeticone is negligible.

#### **4.7 Effects on ability to drive and use machines**

None stated.

#### **4.8 Undesirable effects**

The following CIOMS frequency rating is used, when applicable:

Very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1,000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1,000$ ), very rare ( $< 1/10,000$ ), not known (cannot be estimated from available data).

##### Immune system disorders

*Frequency not known:* hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions.

#### Gastrointestinal disorders

Gastrointestinal side effects are uncommon.

*Uncommon:* diarrhoea or constipation (see section 4.4)

*Frequency not known:* Abdominal pain

Injury, poisoning and procedural complications:

Frequency not known:

Hyperaluminemia (related to Aluminum component).

#### Metabolism and nutrition disorders

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

*Frequency not known:*

Hyperaluminemia

Hypophosphatemia, in prolonged use or at high doses or even normal doses of the product in patients with low-phosphorus diets, which may result in increased bone resorption, hypercalciuria, osteomalacia (see section 4.4).

#### **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. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

or search for MHRA Yellow Card in the Google Play or Apple App Store.

## **4.9 Overdose**

Serious symptoms are unlikely following overdosage.

Reported symptoms of acute overdose with aluminium hydroxide and magnesium salts combination include diarrhoea, abdominal pain, vomiting.

Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk (see section 4.4)

Aluminium and magnesium are eliminated through urinary route; treatment of acute overdose consists of administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Dried aluminium hydroxide gel - antacid

Magnesium hydroxide - antacid

Simeticone - Antifoaming agent/antiflatulent

The antacids are balanced such that gastrointestinal side effects (constipation and diarrhoea) are minimal.

### **5.2 Pharmacokinetic properties**

None stated

### **5.3 Preclinical safety data**

None stated

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Swiss Cream flavour

Lemon flavour

Magnesium stearate

Talc

Citric acid, anhydrous

Glucose, anhydrous  
Saccharin sodium  
Sorbitol (E420)  
Sorbitol liquid non-crystallising (E420)  
Iron oxide yellow (E172)  
Pregelatinised starch (Maize starch)  
Maize starch  
Sucrose  
Mannitol (E421)

## **6.2 Incompatibilities**

None stated.

## **6.3 Shelf life**

Strip packs	36months
Tubes	36months

## **6.4 Special precautions for storage**

Store below 25°C

## **6.5 Nature and contents of container**

### **Strip packs**

Plastic/aluminium strip packs packed in cardboard boxes

Packs of 10,12,20,24,30,36,40,48,50,60,70,72,80,84,90,96,100 tablets are available

### **Tubes**

Paper/foil roll tubes of 12 tablets sold individually or packed in cellophane pillow packs or cardboard cartons

Packs of 12, 24, 36, 48, 72, 144 tablets are available

## **6.6 Special precautions for disposal**

None stated

## **7 MARKETING AUTHORISATION HOLDER**

Opella Healthcare UK Limited, trading as Sanofi  
410 Thames Valley Park Drive,  
Reading,  
Berkshire,  
RG6 1PT,  
United Kingdom.

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 53886/0042

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

11 October 1989 / 28 March 1995

## **10 DATE OF REVISION OF THE TEXT**

19/12/2023