

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

NEUTRAGEL ® PLAIN SUSPENSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The active components of NEUTRAGEL ® per 10 ml are;

- Dried Aluminium Hydroxide gel USP 400mg
- Magnesium hydroxide USP 318mg
- Simethicone 50mg USP (as 30% emulsion)

Preservatives;

- Methylhydroxybenzoate BP 20mg
- Propylhydroxybenzoate BP 2mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pleasant tasting, pink, mint-flavoured oral suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The symptomatic relief of:

1. Dyspepsia.
2. Heartburn.
3. Flatulence.

4.2 Posology and method of administration

Adults

Two to six medicine measures (10 ml – 30 ml) every three hours daily as required. Do not exceed a total daily dose of 180 ml.

Adolescents

One to four medicine measures (5 ml – 20 ml) every three hours daily as required. Do not exceed a total daily dose of 120 ml.

Children under 12yrs

Maximum of one medicine (5 ml) measure three times a day.

4.3 Contraindications

Should not be used in patients who are hypersensitive to any of the active substances or excipients, are severely debilitated or suffering from kidney failure, or hypophosphataemia.

4.4 Special warnings and special precautions for use

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 dementia, microcytic anemia.

Aluminum hydroxide may be unsafe in patients with porphyria undergoing hemodialysis.

This product contains methyl paraben (E218) and propyl paraben (E216); these may cause allergic reactions (possibly delayed).

4.5 Interaction with other FPPs and other forms of interaction

NEUTRAGEL ® 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 oral cephalosporins.

Aluminum hydroxide and citrates may result in increased aluminum levels, especially in patients with renal impairment.

4.6 Pregnancy and lactation

The safety of NEUTRAGEL ® suspension in pregnancy has not been established.

Magnesium is considered as compatible with lactation

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.>

4.8 Undesirable effects

Aluminium hydroxide mixture in common with other aluminium compounds is astringent and may cause nausea, vomiting and constipation. Large doses can cause intestinal obstruction. In large doses it may cause hypophosphataemia.

Magnesium hydroxide may cause diarrhoea, mucosal irritation and absorption of magnesium may occur if there is gastro-intestinal atony or obstruction – hypermagnesaemia may occur. Concurrent use of aluminium-containing antacids with citrate salts can increase aluminium absorption i.e. citrate-containing solutions

4.9 Overdose

Serious symptoms are unlikely following overdosage.

Treatment of magnesium overdose: consider administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal deficiency, haemodialysis or peritoneal dialysis is necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological Classification

Antacids with antiflatulents, ATC Code: A02AF02

Mechanism of action

Dried aluminium hydroxide gel	- antacid
Magnesium Hydroxide	- antacid
Simethicone	- antifoaming agent/antiflatulent

Maalox Plus is a balanced mixture of two antacids and an antiflatulent/antifoaming agent simeticone. The two antacids are magnesium hydroxide which is fast acting and aluminium hydroxide which is a slow acting antacid. The combination produces a fast onset of action and an increase in total buffering time. Aluminium hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of the magnesium hydroxide which is in common with other magnesium salts may cause diarrhoea.

5.2 Pharmacokinetic properties

None stated as NEUTRAGEL® Suspension activity is non-systemic.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the package insert.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The excipients are: methylparaben (E218), propylparaben (E216), hydroxypropylmethylcellulose, sodium hypochlorite, triacetin, saccharin sodium, sorbitol (E420), Peppermint oil, Raspberry Red H1227 and water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 30 °C
Do not freeze

6.5 Nature and contents of container

Natural HDPE plastic bottles and LDPE snap-on closure: 100ml, 200 ml and 2l.

Amber Glass bottles and polypropylene screw-cap: 200 ml

Not all pack sizes may be marketed.

6.6 Instructions for use and handling

No special requirements.

7.

7.1 NAME AND ADDRESS OF MANUFACTURER

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7.2 NAME AND ADDRESS OF PRINCIPAL

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8. REGISTRATION NUMBER

TBA

9. CATEGORY FOR DISTRIBUTION

General Medicines (GS)

10. LAST DATE OF REVIEW

September 2020