

For the Use of Registered Medicinal Practitioners or a Hospital or a Laboratory only

(Magnesium Hydroxide, Dried Aluminium Hydroxide, Activated Dimethicone)

PAN-MPS

1. Name of the medicinal product

PAN-MPS

2. Qualitative and quantitative composition

Each 5 ml contains:

Magnesium Hydroxide	250 mg
Dried Aluminium Hydroxide	250 mg
Activated Dimethicone	50 mg

3. Pharmaceutical form

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

For oral administration:

Adults

5-10ml, 2-3 times in a day taken 20 minutes to 1 hour after meals and at bedtime or as required.

Children

As an appropriate proportion of the adult dose.

Children under 5 years

Maximum of 5ml t.d.s.

Elderly

The normal adult dose is appropriate.

4.3 Contraindications

Hypersensitivity to any constituent of the product.

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-phosphorous 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 dementia, microcytic anemia.

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

4.5 Interaction with other medicinal products and other forms of interaction

PAN-MPS 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 such as tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, levothyroxine, rosuvastatin.

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 risks 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).

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

4.6 Fertility, pregnancy and lactation

The safety of PAN-MPS in pregnancy has not been established.

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 effect 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 known.

4.8 Undesirable effects

Gastrointestinal side-effects are uncommon.

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

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

PAN-MPS 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.

6. Pharmaceutical particulars

6.1 Shelf life

36 Months.

6.2 Special precautions for storage

Store in cool and dry place, protect from light.

6.3 Nature and contents of container

PAN MPS available in Milky white pet bottle of 200ml.

7. Marketed By



ALKEM

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8. DATE OF REVISION OF TEXT

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