

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Indigestion Relief Tablets, Double Action Indigestion Tablets, Antacid Plus Tablets, Gastricalm Tablets, Boots Wind Relief Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredient</u>	<u>Quantity/Unit dose</u>
Dried Aluminium Hydroxide Gel EP (equivalent to 170mg aluminium oxide)	351 mg
Magnesium hydroxide EP	164 mg
Simethicone HSE or Silicone Antifoam M HSE (activated methylpolysiloxane)	25 mg
<u>Excipient(s) with known effect</u>	
Sorbitol	402 mg
Sucrose (icing sugar)	571 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief from discomfort of painful wind, indigestion, heartburn and excess acidity.

4.2 Posology and method of administration

For oral administration.

Adults and children over 12 years: One or two tablets to be sucked or chewed after meals, at bedtime or whenever discomfort is felt.

Children 5 to 12 years: One tablet to be sucked or chewed after meals, at bedtime or whenever discomfort is felt.

Children under 5 years: Not recommended.

Elderly: There is no need for dosage reduction in the elderly.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Hypophosphataemia.

4.4 Special warnings and precautions for use

This product should be used with caution in patients with impaired renal function.

If symptoms persist for more than 5 days, consult your doctor.

Keep all medicines out of the reach of children.

This medicine contains 571 mg of sucrose (as icing sugar) in each tablet. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. May be harmful to the teeth.

This medicine contains 402 mg of sorbitol in each tablet. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

4.5 Interaction with other medicinal products and other forms of interaction

This product may interfere with the absorption of tetracyclines, chloroquine, penicillamine, phenothiazines and quinolone antibacterials, when these are given concomitantly.

4.6 Pregnancy and lactation

There are no adequate human data from the use of aluminium hydroxide and magnesium hydroxide in pregnant women. Studies in animals have not been done. No data are available to suggest any harmful effects in pregnant women, associated with simethicone. Caution should therefore be exercised when taken by pregnant women.

Although some aluminium and magnesium may be secreted in breast milk, the concentration is too small to be harmful. Secretion of simethicone in the breast milk of nursing mothers has not been established but would be most unlikely.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

May occasionally cause diarrhoea or constipation, although the combination of magnesium and aluminium salts minimises these gastrointestinal effects.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms of overdosage include nausea, vomiting, gastrointestinal irritation, diarrhoea/constipation. Treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Aluminium hydroxide and magnesium hydroxide have antacid properties and are used to neutralise gastric acid. Activated methylpolysiloxane (simethicone) has anti-foaming/deflatulent activity by virtue of its ability to change the surface tension of gas bubbles, thereby causing them to coalesce.

5.2 Pharmacokinetic properties

Magnesium hydroxide reacts with hydrochloric acid in the stomach to produce magnesium chloride. Small amounts of magnesium salts may be absorbed and excreted in the urine, otherwise excretion is via the faeces.

Aluminium hydroxide reacts with hydrochloric acid in the stomach to form aluminium chloride, some of which is absorbed. Absorbed aluminium is eliminated in the urine. The majority of aluminium remains in the gastrointestinal tract and forms insoluble poorly absorbed aluminium salts including hydroxide, phosphate, carbonate and fatty acid derivatives, which are excreted in the faeces.

There are no data availability on the pharmacokinetics of activated methylpolysiloxane.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol pdr
Maize starch pdr
Povidone
Isopropyl alcohol

Icing sugar
Magnesium stearate
Peppermint oil Black leaf
Microcrystalline cellulose
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

PVC/PVDC blister heat sealed to aluminium foil.

Pack sizes: 12, 24, 36 & 48

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham
NG2 3AA

8 MARKETING AUTHORISATION NUMBER(S)

PL 00014/0287

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/10/1982 / 23/02/2004

10 DATE OF REVISION OF THE TEXT

20/03/2025