SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Mucogel Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 44 mg dried aluminium hydroxide and 39 mg magnesium hydroxide.

Excipients with known effect

Each ml suspension contains 8.75 mg sorbitol (E 420), 1 mg methyl parahydroxybenzoate (E 218) and 0.5 mg propyl parahydroxybenzoate (E 216).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension.

A white uniform suspension with odour and taste of peppermint.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Mucogel is indicated in adults and children aged 12 years and older.

Antacid therapy in gastric and duodenal ulcer, gastritis, heartburn, gastric hyperacidity. Treatment of indigestion. Relief of symptoms of heartburn and dyspepsia associated with gastric reflux in hiatus hernia, reflux oesophagitis and similar conditions.

4.2 Posology and method of administration

Posology

Adults, elderly and children aged 12 years and older

10 20 ml three times daily 20 minutes to one hour after meals, and at bedtime, or as required.

Children less than 12 years of age

Mucogel should not be used in children less than 12 years of age.

Method of administration

Oral use.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

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

4.4 Special warnings and precautions for use

Paediatric population

In young children the use of magnesium hydroxide can produce a hypermagnesemia, especially if they present with renal impairment or dehydration.

Excipients

This medicine contains 8.75 mg sorbitol (E 420) in each ml. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

This medicine contains methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216) which may cause allergic reactions (possible delayed).

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids inhibit the absorption of tetracyclines and vitamins and should not be taken concomitantly.

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

For Mucogel no clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines

Mucogel has no or negligible influence on the ability to drive and use machines

4.8 Undesirable effects

Gastrointestinal side-effects are uncommon. This formulation minimises the problems of diarrhoea and constipation.

Metabolism and nutrition disorders
Very rare (<1(10,000)
Hypermagnesemia. Observed after prolonged administration of magnesium hydroxide to patients with renal impairment.

Gastrointestinal disorders
Not known (cannot be estimated from the available data)

Abdominal pain.

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

Serious symptoms are unlikely to follow overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for acid related disorders, combinations and complexes of aluminium, calcium and magnesium compounds, ATC code: A02AD01.

The product contains two established antacids, magnesium and aluminium hydroxides with an acid neutralising capacity in excess of 25 ml of 0.1N HC1 consumed, per gram of suspension.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol, liquid (non-crystallising) (E 420)
Mannitol (E 421)
Hydrochloric acid
Methyl parahydroxybenzoate (E 218)
Propyl parahydroxybenzoate (E 216)
Citric acid monohydrate
Simethicone emulsion 30%
Saccharin sodium
Hydrogen peroxide solution 35%
Peppermint oil
Sodium hypochlorite solution, strong
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 2 years.
After opening: 28 days

6.4 Special precautions for storage

Store below 25°C. Do not freeze.

6.5 Nature and contents of container

High density polyethylene (HDPE) bottle with a HDPE closure fitted with a tamper evident ring.

Pack sizes: 100 ml, 120 ml, 125 ml, 200 ml, 240 ml, 250 ml, 300 ml and 500 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 00427/0287

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06/12/1997

Date of latest renewal: 15/01/1999

10 DATE OF REVISION OF THE TEXT

25/01/2022