

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Milk of Magnesia Original Mint Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Magnesium Hydroxide 300mg.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Chewable tablets.

White round tablets embossed 'MM'.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Milk of Magnesia tablets are for the symptomatic relief of indigestion and stomach upset. They can also be used as a laxative in occasional constipation.

4.2 Posology and method of administration

Tablets should be chewed thoroughly for best results.

Stomach upsets:

Adults:

2 to 4 tablets two or three times a day between meals. Do not take more than 16 tablets in 24 hours.

Children:

1 to 2 tablets. Do not give more than 8 tablets in 24 hours.

As a laxative:

Adults:

30-45 ml at bedtime. Repeat nightly, reducing dose each night until constipation is relieved.

Children aged over 2 years:

5-10 ml at bedtime. Repeat nightly reducing the dose until constipation is relieved.

Not to be given to children except on medical advice.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Adequate fluid intake should be maintained during use. If diarrhoea occurs especially in children or the elderly, discontinue use immediately. In case of renal impairment a doctor should be consulted as hypermagnesaemia may occur.

If symptoms persist consult your doctor.

Prolonged continuous use is not recommended.

If you suffer from kidney disease or are under a doctor's care, consult him before using.

If a laxative dose is needed every day or if there is a persistent abdominal pain further medical advice should be sought.

Not to be given to children except on medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

Magnesium hydroxide may interfere locally with the absorption of other drugs taken orally by increasing gastric pH. This can be avoided by giving other drugs 2-3 hours before the administration of magnesium hydroxide on the advice of a doctor.

Milk of Magnesia may interact with tetracycline, digoxin, dicoumarol and cimetidine.

4.6 Pregnancy and lactation

Magnesium crosses the placenta and, as with all drugs, use during pregnancy and lactation should be avoided unless on the advice of a doctor. Magnesium is excreted in small amounts into breast milk, however, use of Milk of Magnesia is considered to be compatible with breast feeding.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Diarrhoea may occur which is dose related.

4.9 Overdose

Overdose may cause diarrhoea and, where renal impairment exists, hypermagnesaemia may occur.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Magnesium hydroxide is practically insoluble in water and solution is not effected until the hydroxide reacts with hydrochloric acid in the stomach to form magnesium chloride. Its neutralising action is almost equal to that of sodium bicarbonate. When the dose is in excess of that required to neutralise the acid the intragastric pH may reach pH 8 or 9. Acid rebound following magnesium hydroxide is clinically insignificant.

Magnesium hydroxide has an indirect cathartic effect resulting from water retention in the intestinal lumen.

5.2 Pharmacokinetic properties

Magnesium hydroxide exerts its antacid therapeutic effect rapidly within the gastro-intestinal tract following oral administration and this action is therefore independent of pharmacokinetic properties. Following oral administration, about one third to half the magnesium is absorbed very slowly from the small intestine. Magnesium salts are excreted mainly in the urine with small amounts in the faeces and saliva.

5.3 Preclinical safety data

Magnesium hydroxide has been used for many years and no further data are presented in this section.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sorbitol
Magnesium Stearate
Peppermint Flavour P440.47915

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Store below 25°C in the original container.

6.5 Nature and contents of container

Milk of Magnesia tablets are packed in PVDC coated PVC blister packs which are further packed into cardboard cartons containing 24, 72 or 120 tablets or blister packs of 200µm clear PVC sealed to 20µm aluminium foil further packed into cardboard cartons containing 24, 72 or 120 tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare (Ireland) Ltd
Stonemasons Way
Rathfarnham
Dublin 16

8 MARKETING AUTHORISATION NUMBER

PA 678/31/4

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 20 August 2002

10 DATE OF REVISION OF THE TEXT

May 2005