SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade Name> <Strength> oral suspension

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Magnesium hydroxide 8% w/w, equivalent to magnesium oxide 5.5% w/v.

Excipient(s) with known effect:

<Regarding the approval>

For a full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Oral suspension

<Regarding the approval>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

For oral use for the relief of mild constipation.

* 1. Posology and method of administration

*For adults (including the elderly):*

25 to 50 ml orally as required (maximum daily dose 50 ml)

*For children aged 6-12 years:*

10 to 25 ml orally as required (maximum daily dose 25 ml)

*For children aged 1-6 years:*

5 to 10 ml orally as required (maximum daily dose 10 ml)

Not recommended for children under 1 year of age.

Not recommended in cases of renal impairment of debilitation.

* 1. Contraindications

Should not be used where there are known or suspected acute gastro- intestinal conditions, or renal or hepatic impairment.

* 1. Special warnings and precautions for use

Label warnings:

* Store below 25°C.
* Do not freeze.
* Shake well before use.
* Keep out of the sight and reach of children.
* Chronic use may result in hypermagnesia.
  1. Interaction with other medicinal products and other forms of interaction

The antacid properties of this preparation can lead to reduced absorption of diflusinal, azithromycin, ciprofloxacin, isoniazid, norfloxacin, ofloxacin, pivampicillin, rifampicin and most tetracyclines. Also reduces absorption of phenytoin, itraconazole, ketoconazole, fosinopril, chloroquine, hydroxychloroquine, phenothiazines, biphosphonates and penicillamine. The use of this product is not advised during dipyridamole therapy. The excretion of aspirin is increased and quinidine is decreased in alkaline urine which may occur with use of this product.

* 1. Fertility, pregnancy and lactation

There is not or inadequate evidence of safety of use during pregnancy and lactation but has been used for many years without ill effect. As with all drugs, use during early pregnancy should be avoided. Can be used during late pregnancy and during lactation.

* 1. Effects on ability to drive and use machines

Does not affect ability to drive and use machines.

* 1. Undesirable effects

Can cause colic.

* 1. Overdose

Serious symptoms are unlikely following overdose. Discontinue medication and correct fluid balance if necessary.

Hypermagnesaemia may be treated with intravenous calcium salts but only under medical supervision.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Antacid properties in doses of 500-750 mg

Laxative properties in larger doses.

* 1. Pharmacokinetic properties

The magnesium hydroxide acts as a saline laxative in the intestine. Any absorbed magnesium is rapidly excreted in the urine. It has the benefit over magnesium carbonate of not causing side effects associated with formation of carbon dioxide in the stomach.

* 1. Preclinical safety data

None stated.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<Regarding the approval>

* 1. Incompatibilities

None known

* 1. Shelf life

<Regarding the approval>

* 1. Special precautions for storage

<Regarding the approval>

* 1. Nature and contents of container

<Regarding the approval>

* 1. Special precautions for disposal

<Regarding the approval>

1. MARKETING AUTHORISATION HOLDER

<Regarding the approval>

1. MARKETING AUTHORISATION NUMBER(S)

<Regarding the approval>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Regarding the approval>

1. DATE OF REVISION OF THE TEXT1

<Regarding the approval>