SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade name> <strength> suspension

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

Dried aluminium hydroxide and magnesium hydroxide 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.

* 1. 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:*

Dried aluminium hydroxide and magnesium hydroxide should not be used in children less than 12 years of age.

Method of administration

Oral

* 1. 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.
  1. 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 <Regarding the approval>

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’.

* 1. 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.

* 1. Fertility, pregnancy and lactation

For dried aluminium hydroxide and magnesium hydroxide 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.

* 1. Effects on ability to drive and use machines

Dried aluminium hydroxide and magnesium hydroxide has no or negligible influence on the ability to drive and use machines.

* 1. Undesirable effects

Gastrointestinal side-effects are uncommon. This formulation minimizes 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 Health Product Vigilance Center; HPVC Thai FDA.

* 1. Overdose

Serious symptoms are unlikely to follow overdosage.

1. PHARMACOLOGICAL PROPERTIES
   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.

* 1. Pharmacokinetic properties

Not applicable.

* 1. 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.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<Regarding the approval>

* 1. Incompatibilities

Not applicable.

* 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>