SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade Name> <Strength> emulsion BP

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Liquid paraffin BP 25% v/v

Magnesium hydroxide 6% w/w

Excipient(s) with known effect:

<Regarding the approval>

For a full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Emulsion

<Regarding the approval>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

For oral use for the temporary relief of constipation.

* 1. Posology and method of administration

For adults over 12 years (including the elderly)

5 to 20 ml orally as required (maximum daily dose 20 ml)

For Children 3-12 years of age

5 to 15 ml orally as required (maximum daily dose 15 ml)

* 1. Contraindications

Not recommended for children under 3 years of age.

Do not use when intestinal obstruction is suspected.

* 1. Special warnings and precautions for use
* Avoid prolonged use.
* Caution should be exercised in administering this product to the elderly with possible renal impairment.
* Keep out of the sight and reach of children.
* Store below 25°C
* Do not freeze.
  1. Interaction with other medicinal products and other forms of interaction

There may be interference with the absorption of fat soluble vitamins.

* 1. Fertility, pregnancy and lactation

Avoid in early pregnancy or lactation.

* 1. Effects on ability to drive and use machines

Does not affect ability to drive and operate machinery.

* 1. Undesirable effects

Anal seepage of paraffin and consequent anal irritation can occur after prolonged use.

Granulomatous reactions caused by absorption of small quantities of liquid paraffin.

Lipoid pneumonia (by accidental inhalation) may occur and therefore caution is required in patients with swallowing difficulties.

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

If large quantities are ingested, withdraw medication. Supportive treatment may be required.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

Liquid paraffin, taken internally, acts as a lubricant and is widely used to alleviate constipation.

Magnesium hydroxide has antacid properties and also acts as a mild saline laxative.

* 1. Pharmacokinetic properties

There is some evidence that magnesium salts may cause decreased absorption of the active ingredients of other medications. e.g. digoxin. Excessive use of liquid paraffin may lead to anal seepage and irritation and may, if emulsified, give rise to granulatomous reactions.

* 1. Preclinical safety data

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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>