SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade Name> <Strength> suppositories

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains 2800 mg Glycerol

Excipient(s) with known effect:

<Regarding the approval>

For a full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Amber coloured suppository, of nominal weight 4 g intended for rectal administration.

<Regarding the approval>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

For occasional use as a stimulant laxative for the treatment of constipation.

* 1. Posology and method of administration

*Adults and the elderly:*

One 4 g suppository, to aid insertion the suppository tip should be moistened with water before use. No reduction in adult dosage is necessary for elderly patients.

*Infants and Children:*

Not recommended.

Method of administration

For rectal use.

* 1. Contraindications
* Hypersensitivity to the active substance or to any of the excipients.
* The product is contraindicated if there is intestinal obstruction or blockage.
  1. Special warnings and precautions for use

The product is intended for occasional use only. Prolonged or excessive use of the product is not recommended as this may cause diarrhoea. Use of this product may interfere with glucose control in diabetic patients. If symptoms persist consult a doctor.

* 1. Interaction with other medicinal products and other forms of interaction

None stated.

* 1. Fertility, pregnancy and lactation

No evidence of harmful affects available. However, best avoided during the first trimester of pregnancy. May be used during breast feeding.

* 1. Effects on ability to drive and use machines

None stated.

* 1. Undesirable effects

Use of the product may occasionally cause abdominal cramps. Glycerol can cause irritation when given rectally.

* 1. Overdose

Overdosage via rectal route is unlikely. However, if ingested treat symptomatically.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

ATC code A06AX01

Glycerol is commonly classified as an osmotic laxative but may act additionally or alternatively by promoting peristalsis and evacuation of the lower bowel by virtue of a mild irritant effect. Glycerol suppositories possess also lubricating and faecal softening actions.

* 1. Pharmacokinetic properties

Glycerol following rectal administration is poorly absorbed.

* 1. Preclinical safety data

No additional pre-clinical data of relevance to the prescriber.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<Regarding the approval>

* 1. Incompatibilities

None stated.

* 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>