

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Glycerol 1g Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains: 700mg Glycerol

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suppository

Amber coloured suppository, of nominal weight 1 g.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Suppositories for rectal insertion.

Infants

One suppository, to aid insertion the suppository tip should be moistened with water before use.

4.3 Contraindications

§ The product is contraindicated if there is intestinal obstruction or blockage.

§ Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

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

4.5 Interaction with other medicinal products and other forms of interactions

None stated.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

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

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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code A06AX01

Glycerol is an osmotic dehydrating agent with hygroscopic and lubricating properties.

Glycerol acts by promoting peristalsis and evacuation of the lower bowel by virtue of a mild irritant effect.

5.2 Pharmacokinetic properties

Glycerol following rectal administration is poorly absorbed.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do below 25°C in a dry place.

6.5 Nature and contents of container

Heat sealed cavities composed of Polyvinyl Chloride (PVC) Coated with Polyvinylidene Chloride (PVDC) and laminated with polyethylene (PE), each containing one x 1g suppository in strips of 6. The strips are packed in cardboard cartons. Pack size contains 12 suppositories.

6.6 Special precautions for disposal and other handling

Wash hands before opening individual packaging. The suppository is shaped for rectal insertion, ensure the tip of the suppository is inserted first. The tip should be moistened with a little cold water to aid insertion.

7 MARKETING AUTHORISATION HOLDER

Ethypharm
194 Bureaux de la Colline - Bâtiment D
92213 Saint-Cloud Cedex
France

8 MARKETING AUTHORISATION NUMBER

PA0549/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 February 1993

Date of last renewal: 25 February 2008

10 DATE OF REVISION OF THE TEXT

June 2019