Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Glycerol 4g Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains 2.8 grams of glycerol (equivalent to 70 % w/w).
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suppository.
Amber-coloured suppository, of nominal weight 4 g.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Suppositories for rectal insertion.

Adults, the elderly and children of 12 years and over
One suppository, to aid insertion the suppository tip should be moistened with water before use.

Children under 12 and infants
Not recommended.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

The product is intended for occasional use only. Prolonged use is not recommended.

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 interaction

None stated.

4.6 Fertility, pregnancy and lactation

No evidence of harmful affects available. However, best avoided during the first trimester of pregnancy.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Use of the product may occasionally cause abdominal cramps.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 is readily absorbed from the intestine and is metabolised to carbon dioxide and glycogen or used by the human body in the synthesis of body fats.

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 not store above 25°C.
Store in the outer carton

6.5 Nature and contents of container

Heat-sealed, cavities composed of Polyvinyl Chloride (PVC) coated with Polyvinylidene Chloride (PVDC) laminated with polyethylene (PE), each containing one 4 g suppository, in strips of six. The strips are packed in cardboard cartons.
Pack sizes available: 12 suppositories.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ethypharm

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92213 Saint-Cloud Cedex
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8 MARKETING AUTHORISATION NUMBER

PA0549/028/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 October 1991

Date of last renewal: 18 October 2006

10 DATE OF REVISION OF THE TEXT

September 2025