

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Glycerol 2g Suppositories

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains: 1400mg Glycerol

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Suppository

Amber coloured suppository, of nominal weight 2 g.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

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

### 4.2 Posology and method of administration

Suppositories for rectal insertion.

#### Children

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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**

Store 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 2 g 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

11 June 2019

CRN008YGJ

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**8 MARKETING AUTHORISATION NUMBER**

PA0549/028/002

**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