

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Babylax 1.8 g Rectal Solution.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glycerol (85%) 1.8 g per applicator.

Excipients: Each applicator contains 0.36mg of benzalkonium chloride.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Rectal solution.

Clear, colourless, rectal solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

In the treatment of constipation.

### 4.2 Posology and method of administration

For rectal use only.

Under 3 months: ½ to 1 applicator.

Over 3 months up to 6 years: 1 applicator.

Children over 6 years: 1 - 2 applicators.

Adults and elderly: 1 - 2 applicators.

### 4.3 Contraindications

None.

### 4.4 Special warnings and precautions for use

If constipation persists, consult your doctor.

### 4.5 Interaction with other medicinal products and other forms of interaction

None.

### 4.6 Fertility, pregnancy and lactation

None.

### 4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Prolonged use may lead to irritation of the anal canal.

4.9 Overdose

None.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Glycerol is a trivalent alcohol. When glycerol is given rectally, it promotes peristalsis and evacuation of the lower bowel by virtue of its irritant action, so that defecation stimulus is increased.

5.2 Pharmacokinetic properties

There is a slight absorption of glycerol from the rectum. The elimination of absorbed glycerol is via the kidneys.

5.3 Preclinical safety data

LD50	Guinea pig	oral	7.75	g/kg
LD50	Mouse	oral	4.1	g/kg
LD50	Rat	oral	12.6	g/kg
LD50	Mouse	iv	6.2	g/kg
LD50	Rat	iv	5.6	g/kg
LD50	Mouse	ip	8.98	g/kg
LD50	Rat	ip	8.3	g/kg
LD50	Mouse	sc	0.09	g/kg
LD50	Rat	sc	0.1	g/kg

(Registry of toxic Effects of Chemical Substances 1987)

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride  
Macrogol 400  
Carbomer  
Sodium hydroxide  
Disodium Edetate  
Water for Injections

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf Life

Unopened: 3 years.

Once opened: Use immediately and discard any unused solution.

## 6.4 Special precautions for storage

Do not store above 25°C.

## 6.5 Nature and contents of container

Low density polyethylene tube with cannula.

### Package sizes:

3 x 3.6 g applicators

6 x 3.6 g applicators

Not all pack sizes may be marketed.

## 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

For use under medical supervision.

For single use only - Discard immediately after use.

Remove the cap from the applicator and invert the cap. With the point in the cap, pierce the opening of the nozzle of the applicator. Grease cannula and insert gently into the rectum (as with a thermometer when taking a temperature). Expel contents by squeezing. The maximum effect is obtained if evacuation is restrained for as long as possible; in the case of small babies keep legs together for two to three minutes.

## 7 MARKETING AUTHORISATION HOLDER

Bausch & Lomb UK Limited  
106 London Road  
Kingston-Upon-Thames  
Surrey  
KT2 6TN  
UK

## 8 MARKETING AUTHORISATION NUMBER

PA 555/9/1

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 December 1992

Date of last renewal: 17 December 2007

## **10 DATE OF REVISION OF THE TEXT**

November 2010