

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

CARBALAX SUPPOSITORIES

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains:

Sodium acid phosphate anhydrous

(equivalent to Sodium Acid Phosphate Ph.Eur. 1.69g) 1.30g

Sodium Bicarbonate Ph.Eur. 1.08g

## 3 PHARMACEUTICAL FORM

Suppository for rectal administration

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Chronic simple constipation. Constipation due to prolonged bed-rest or to drugs. Bowel evacuation before childbirth, surgery, sigmoidoscopy, radiological examination and post-operatively. To avoid discomfort associated with straining. To regularise bowel movement and keep stools to normal consistency in local anal conditions such as haemorrhoids, fissures and fistulae.

### 4.2 Posology and method of administration

Adults and the Elderly:

Administer one suppository 30 minutes before evacuation is required.

Children under 12:

Not recommended.

#### **4.3 Contraindications**

Conditions where any bowel medication for the relief of constipation is contraindicated.

#### **4.4 Special warnings and precautions for use**

The suppository should be moistened with water, not lubricated with oil before insertion.

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

None known.

#### **4.6 Pregnancy and lactation**

No restriction.

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

None known.

#### **4.8 Undesirable effects**

Side effects are unlikely.

##### **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### **4.9 Overdose**

Overdose has not been reported.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Carbalax Suppositories function by a physical induction of reflex bowel evacuation caused when carbon dioxide is liberated when the suppository contacts moisture. Bowel action will usually take place within half an hour of administration.

### **5.2 Pharmacokinetic properties**

If any bicarbonate is not converted to carbon dioxide it may be absorbed and excreted as bicarbonate ions in the urine. Any absorbed phosphate will also eventually be excreted in the urine.

### **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber that might add to the safety data provided in other sections of this SPC.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Polyethylene glycol 1500

**6.2 Incompatibilities**

None stated.

**6.3 Shelf life**

One year.

**6.4 Special precautions for storage**

Store below 25°C in a dry place.

**6.5 Nature and contents of container**

Each suppository is contained in a PVC shell. The shells are supplied in strips of 12 in a cardboard carton of 12 or 60 suppositories.

**6.6 Special precautions for disposal**

None stated.

**7 MARKETING AUTHORISATION HOLDER**

CHEMIDEX PHARMA LIMITED

8a CRABTREE ROAD

EGHAM

SURREY

TW20 8RN

UNITED KINGDOM

**8    MARKETING AUTHORISATION NUMBER(S)**

PL 17736/0103

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

02 May 1990 / 22 September 1997

**10   DATE OF REVISION OF THE TEXT**

17/02/2026