

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Lecicarbon C Suppository

For use in children

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository of Lecicarbon C Suppository contains

Sodium hydrogen carbonate 0.250 g, sodium dihydrogen phosphate 0.340 g.

Lecicarbon C Suppository contains (3-sn-Phosphatidyl)cholin (= soybean oil, lecithines, as phosphatides, 18 mg phosphatides per suppository).

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Suppository.

Lecicarbon C Suppository is a cream coloured, homogenous, torpedo shaped suppository; packed in PVC/PE blisters of five, with batch number and expiry date embossed.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Short term treatment of constipation due to various causes (e.g. nutrition poor in fibres, lack of physical activity, as well as diseases requiring easy defaecation).

Emptying the colon before diagnostic or therapeutic procedures in the rectum.

### 4.2 Posology and method of administration

Posology

Children:

Unless otherwise directed, insert one suppository into the rectum when needed. If necessary, this can be repeated after 30 – 60 minutes.

Adults:

Lecicarbon C should not be used in adults. A product with a higher strength is available.

Lecicarbon C Suppository is safe to use for long periods and is not habit-forming.

#### Method of administration

Remove from the packaging by separating one suppository from the strip. Grasp the plastic tabs in both hands and pull apart. Insert one suppository into the rectum. Insertion is made easier if the suppository is first dipped into water. Do not use oil or petroleum jelly as a lubricant.

It may be necessary to press the two halves of the child's bottom together to avoid the suppository being immediately expelled.

The onset of action is between 15 and 30 minutes.

### **4.3 Contraindications**

This medicinal product must not be used in cases of ileus (intestinal obstruction), in case of all anal and rectal region diseases, that can lead to an excessive absorption of carbon dioxide, especially in children and infants, and in case of hypersensitivity against soy bean, pea nut or to one of the excipients of Lecicarbon C Suppository. In the presence of toxic megacolon (pathological enlargement of the end of the large intestine due to various causes) the product should only be used with explicit permission of the treating physician.

This medicinal product contains (3-sn-Phosphatidyl)cholin (= Soybean oil, lecithines). If you are allergic to peanut or soya, do not use this medicinal product.

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

None known and not likely in view of the pharmacological properties.

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

None known.

### **4.6 Fertility, pregnancy and lactation**

#### **Pregnancy**

Lecicarbon C Suppository may be used during pregnancy after a careful risk to benefit evaluation of the treating physician. Based on current knowledge the effect of the expanding volume of the carbon dioxide may be negligible.

#### **Breastfeeding**

Lecicarbon C Suppository may be used during breastfeeding. The developed carbon dioxide will not be excreted in the human breast milk.

#### **Fertility**

There are no data on the effects of Lecicarbon C Suppository on human fertility. Effects on male and female fertility have not been evaluated in animal studies.

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

None known.

#### **4.8 Undesirable effects**

Rarely Soya Lecithin has been known to cause allergic reactions. The insertion of the suppository can very occasionally cause a slight burning sensation, which quickly disappears.

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 Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

#### **4.9 Overdose**

Not known.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Carbon dioxide producing drugs, ATC code: A06AX02

Lecicarbon C Suppository functions by a physical induction of reflex bowel evacuation caused when carbon dioxide is liberated when the suppository contacts moisture.

Carbon dioxide (CO<sub>2</sub>) is the main constituent of the gaseous products of metabolism which are formed on digestion of the intestinal contents. Of all the intestinal gases, it is the one which causes the most intense stimulation of movement of the rectum.

Lecicarbon C Suppository overcomes constipation according to the same principle, exclusively via the supply of CO<sub>2</sub> which is slowly released in fine bubbles from the suppositories after they are inserted into the rectum. The CO<sub>2</sub> activates the intestinal movement and triggers the evacuation process within 15 – 30 minutes, without causing irritation, cramps or other side effects.

### **5.2 Pharmacokinetic properties**

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

### **5.3 Preclinical safety data**

Preclinical studies were not conducted. Systemic toxic effects are not to be expected. Carbon dioxide is a physiological intestinal gas.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

- (3-sn-Phosphatidyl)cholin (= soya lecithin, phosphatides),
- hard fat and
- silica, colloidal anhydrous.

### **6.2 Incompatibilities**

None stated.

### **6.3 Shelf life**

18 months.

### **6.4 Special precautions for storage**

Do not store above 25 °C.

### **6.5 Nature and contents of container**

Each suppository is contained in a twin layer PVC and foil shell. The shells are supplied in strips of 5 suppositories in a cardboard carton.  
Original Pack Sizes containing 5 or 10 suppositories of Lecicarbon C Suppository.  
Hospital Pack Sizes containing 5x10 suppositories of Lecicarbon C Suppository.

### **6.6 Special precautions for disposal**

No special requirements.

## **7. MARKETING AUTHORISATION HOLDER**

athenstaedt GmbH & Co KG  
Am Beerberg 1  
35088 Battenberg (Eder)  
Germany

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 28418/0002

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

24/02/2011 / 30/01/2012

**10 DATE OF REVISION OF THE TEXT**

11/10/2017