SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lecicarbon A Suppository

For use in adults

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository of Lecicarbon A Suppository contains

Sodium hydrogen carbonate 0.500 g, sodium dihydrogen phosphate 0.680 g.

Lecicarbon A Suppository contains (3-sn-Phosphatidyl)cholin (= soybean oil, lecithines, as phosphatides, 36 mg phosphatides per suppository).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suppository.

Lecicarbon A 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

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

Children:
Lecicarbon A should not be used in children.

Lecicarbon A 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.
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 A 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 A 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 A 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 A 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

4.9 Overdose

Not known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

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

Carbon dioxide (CO_2) 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 A Suppository overcomes constipation according to the same principle, exclusively via the supply of CO2 which is slowly released in fine bubbles from the suppositories after they are inserted into the rectum. The CO2 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

24 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 or 6 suppositories in a cardboard carton.
Original Pack Sizes containing 5, 10, 30 or 100 suppositories of Lecicarbon A Suppository.
Hospital Pack Sizes containing 50x10 or 500 suppositories of Lecicarbon A 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 28418/0001

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24/02/2011 / 30/01/2012

10 DATE OF REVISION OF THE TEXT

17/02/2021