

Lecicarbon® C Suppository

For use in children

Active substances: sodium hydrogen carbonate, sodium dihydrogen phosphate.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

1. What Lecicarbon® C Suppository is and what it is used for
2. What you need to know before you use Lecicarbon® C Suppository
3. How to use Lecicarbon® C Suppository
4. Possible side effects
5. How to store Lecicarbon® C Suppository
6. Contents of the pack and other information

1. WHAT LECICARBON® C SUPPOSITORY IS AND WHAT IT IS USED FOR

Lecicarbon® C Suppository is used for various forms of constipation, e.g. intake of food not containing enough fibre, lack of physical activity and in diseases which need easy defaecation. Lecicarbon® is also used for emptying the bowels before surgery or diagnostic procedures in the rectum.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LECICARBON® C SUPPOSITORY

Do not use Lecicarbon® C Suppository

- if you are allergic (hypersensitive) to sodium hydrogen carbonate, sodium dihydrogen phosphate or any of the other ingredients of Lecicarbon® C Suppository.
- in cases of intestinal obstruction (ileus).

Warnings and precautions

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.

Other medicines and Lecicarbon® C Suppository

You can use Lecicarbon® C Suppository while taking other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Lecicarbon® C Suppository with food and drink

There are no special precautions required.

Pregnancy, breast-feeding and fertility

Pregnancy:

You may use Lecicarbon® C Suppository during pregnancy after consulting your treating physician.

Breast feeding:

You may use Lecicarbon® C Suppository during breast feeding.

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.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Lecicarbon® C Suppository has no influence on the ability to drive or to use machines.

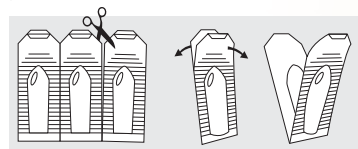
Attention must be paid to the fact that the effect (defecation) is expected 15 to 30 minutes after application.

Lecicarbon® C Suppository contains (3-sn-phosphatidyl)choline (from soybean oil, lecithines)

If you are allergic to peanut or soya, do not use this medicinal product.

3. HOW TO USE LECICARBON® C SUPPOSITORY

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.



Unless otherwise directed, insert one suppository into the rectum (back passage) when needed. If necessary, this can be repeated after 30 to 60 minutes.

Before Lecicarbon® C Suppository can be used, remove from the packaging by separating one suppository from the strip at the perforation. Grasp the plastic tabs in both hands and pull apart. Insert the suppository into the

anus (back passage). Insertion is made easier if the suppository is first dipped into water. For a child, 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 after 15 to 30 minutes. Do not use oil or petroleum jelly as a lubricant.

Lecicarbon® C Suppository is suitable for children under 12 years of age. Lecicarbon® C Suppository is not suitable for use in adults.

Lecicarbon® C Suppository is safe to use for long periods and is not habit-forming. However, a doctor should always be consulted in cases of chronic constipation.

If you use more Lecicarbon® C Suppository than you should

The usual dose is one suppository. If necessary, the administration can be repeated after 30-60 minutes. There is no danger if you exceed this dose, but it is not sensible to administer more than two suppositories.

If you forget to use Lecicarbon® C Suppository

Lecicarbon® C Suppository is only used when needed.

If you stop using Lecicarbon® C Suppository

Lecicarbon® C Suppository is only used when needed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lecicarbon® C Suppository can cause side effects, although not everybody gets them.

Lecicarbon® C Suppository does not normally cause problems (side effects). Sometimes, in rare cases, the insertion of the suppository can cause a slight burning sensation, which quickly disappears.

Reporting of side effects

You should tell your doctor or pharmacist if you experience any side effects not listed in this leaflet. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0800 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

5. HOW TO STORE LECICARBON® C SUPPOSITORY

Keep this medicine out of the reach and sight of children.

Do not store above 25° C.

Do not use this medicine after the expiry date which is stated on the carton and on the blister shell after "EXP".

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lecicarbon® C Suppository contains

- The active substances are sodium hydrogen carbonate and sodium dihydrogen phosphate.
- The other ingredients are soybean oil, lecithines ([3-sn-phosphatidyl] choline) hard fat and silica, colloidal anhydrous.

What Lecicarbon® C Suppository looks like and contents of the pack

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.

It is available in original pack sizes containing 5 or 10 suppositories and in hospital pack sizes with 5x10 suppositories. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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

Manufacturer

Haupt Pharma Livron S.A.S., 1 Rue Comte de Sinard, F-26250 Livron-Sur-Drôme, France
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Distributor

Aspire Pharma Limited, Unit 4, Rotherbrook Court, Bedford Road, Petersfield, GU32 3QG, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany: Lecicarbon® E/K CO₂-Laxans zwei/drei

United Kingdom: Lecicarbon® A/C Suppository

Hungary: Lecicarbon® Felnőtt végbélkúp/Lecicarbon® Gyermekek végbélkúp

Luxembourg: Lecicarbon® E/K

Slovenia: Lecicarbon® za odrasle 500 mg/680 mg svečke / Lecicarbon® za otroke 250 mg/340 mg svečke

This leaflet was last approved in 10/2017.

What are the properties of Lecicarbon® C Suppository?

Carbon dioxide (CO₂) 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 CO₂ which is slowly released in fine bubbles from the suppositories after they are inserted into the rectum.

The CO₂ which is produced in excess, activates intestinal movement and triggers the evacuation reflex generally within 15 to 30 minutes, without causing irritation, cramps or other side effects.