

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S0****LEBALAX 5 mg suppositories****LEBALAX 10 mg suppositories****Bisacodyl****Sugar free.****Read all of this leaflet carefully because it contains important information for you**

LEBALAX is available without a doctor's prescription, for you to treat a minor illness. Nevertheless, you still need to use or give your child LEBALAX carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LEBALAX with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your or your child's symptoms worsen or do not improve after 5 days.

What is in this leaflet

1. What LEBALAX is and what it is used for
2. What you need to know before you use or give your child LEBALAX
3. How to use or give your child LEBALAX
4. Possible side effects
5. How to store LEBALAX
6. Contents of the pack and other information

1. What LEBALAX is and what it is used for

LEBALAX suppositories contain the active ingredient bisacodyl which belongs to a group of medicines called laxatives.

LEBALAX is used for the short-term relief from occasional constipation.

2. What you need to know before you use or give your child LEBALAX

Do not use or give your child LEBALAX if you or your child:

- Is hypersensitive (allergic) to bisacodyl or any of the other ingredients of LEBALAX listed in section 6 of this leaflet.
- Has severe dehydration.
- Has a bowel condition called “ileus” (blockage in the intestine).
- Has a serious abdominal condition, such as appendicitis.
- Has a blocked bowel (intestinal obstruction).
- Has inflammation of the bowel (small or large intestine).
- Has cracking skin around the back passage (anal fissures).
- Has inflammation or ulcers around the back passage (ulcerative proctitis).

Warnings and precautions

Special care should be taken with LEBALAX:

- If you or your child has severe abdominal pain with nausea and vomiting.

Overuse of laxatives may damage your or your child’s health by causing:

- Harm to the intestinal function, including a ‘lazy bowel’ which may lead to long-term constipation.
- Disturbances of electrolyte and mineral balances. This can affect the proper functioning of the nerves and muscles, including those of the bowel.
- Low levels of potassium in the blood (causing tiredness, dizziness, muscles weakness and changes in the way your or your child’s heart beats).
- Severe dehydration (causing tremors, weakness, blurry vision, fainting, thirst). Dehydration often requires medical treatment.
- Inflammation of the rectum.

LEBALAX does not help with weight loss. It does not reduce the absorption of calories or nutrients. LEBALAX can cause watery stools (diarrhoea), abdominal cramps and dehydration. Dehydration can seem like weight loss.

It is recommended to use changes in diet and bulk forming medicines to control constipation before using or giving your child LEBALAX.

Children and adolescents

LEBALAX 5 mg should not be used by children without medical advice.

Other medicines and LEBALAX

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

It is important to tell you doctor or pharmacist if you or your child is taking:

- Water tablets (diuretics).
- Cortisone-like medicines (used to treat inflamed areas of your body), such as prednisolone.
- Other laxative medicines.

LEBALAX with food and drink

No information of relevance available.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using LEBALAX.

Driving and using machines

Your ability to drive and use machines may be affected by side effects, such as dizziness. Do not drive a vehicle or operate machinery until you know how LEBALAX affects you.

3. How to use or give your child LEBALAX

Do not share medicines prescribed for you with any other person.

Always use LEBALAX exactly as described in this leaflet or as your doctor, pharmacist or health care provide has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and children 12 years and over

The usual dose is one 10 mg suppository as a single daily dose.

Children 1 - 12 years

The usual dose is one 5 mg suppository as a single daily dose.

LEBALAX should not be used for more than 5 days. If you or your child needs laxatives every day, or if you or your child has abdominal pain which does not go away, you should consult your doctor.

How to use the suppositories

The suppositories should only be used in your or your child's back passage.

1. To remove a suppository, tear one from the strip along the perforations, then peel the plastic from it by grasping the two halves of the wrapping at the tip of the suppository and pulling them gently apart.
2. Lie on one side and pull your knees up towards your chest. Keep one leg drawn up more than the other.
3. Use your first finger (index finger) or middle finger to push in the suppository.
4. Gently push the suppository as far as possible into your back passage, pointed end first.
5. Once it is as far as it will go, push it side-ways to make sure it touches the wall of the bowel.
6. Lower your legs to a comfortable position whilst the suppository is retained in place.

7. Keep the suppository inside you or your child for at least 30 minutes.

If you feel the suppository might come out straight away:

You may not have put it in high enough. Push it in as far as possible. Try to keep it in for 30 minutes, even if you feel like you urgently need to go to the toilet. This is how long it takes to work.

If you use or give your child more LEBALAX than you should

In the event of overdose, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

4. Possible side effects

LEBALAX can have side effects.

Not all side effects reported for LEBALAX are included in this leaflet. Should your or your child's general health worsen or if you or your child experience any untoward effects while using LEBALAX, please consult your health care provider for advice.

If any of the following happens, stop using LEBALAX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you or your child has them, you or your child may have had a serious reaction to LEBALAX and may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- colitis (inflammation of the large intestine causing abdominal pain and diarrhoea),
- blood in the stool.

These are all serious side effects. You or your child may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- pain or cramps in the stomach area,
- nausea (feeling sick),
- diarrhoea.

Less frequent side effects:

- dehydration (increased thirst, dry mouth, swollen tongue, weakness, confusion),
- dizziness,
- vomiting (being sick),
- discomfort in the stomach or back passage area.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you or your child get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04**

Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LEBALAX.

5. How to store LEBALAX

- Store at or below 25 °C, protected from light and moisture.
- Keep the blister strip(s) in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LEBALAX contains

The active substance in LEBALAX is bisacodyl.

LEBALAX 5 mg: Each suppository contains 5 mg bisacodyl.

LEBALAX 10 mg: Each suppository contains 10 mg bisacodyl.

The other ingredient is witepsol S-55 (hard fat).

What LEBALAX looks like and contents of the pack

LEBALAX 5 mg: White to off-white spindle suppository.

LEBALAX 10 mg: White to off-white spindle suppository.

LEBALAX suppositories are packed in PVC-based peel off blister strips containing 5 suppositories per blister strip, placed in an outer carton.

Pack size: 10 suppositories.

Holder of certificate of registration

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