1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

PROPRIETARY NAME AND DOSAGE FORM

LENOLAX PAEDIATRIC

LENOLAX

Enema

Read all of this leaflet carefully because it contains important information for you.

LENOLAX is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use LENOLAX carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LENOLAX with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

WHAT LENOLAX CONTAINS

LENOLAX PAEDIATRIC and LENOLAX:

Each 1 ml contains:

180,87 mg sodium dihydrogen phosphate dihydrate equivalent to 160 mg sodium dihydrogen phosphate monohydrate and 80,142 mg disodium phosphate dodecahydrate equivalent to 60 mg disodium phosphate heptahydrate.

Preservatives: Methyl hydroxybenzoate 0,048 % *m/v,* sodium benzoate 0,096 % *m/v.*

LENOLAX PAEDIATRIC contains 103 millimoles of sodium per 64 ml dose.

LENOLAX contains 217,3 millimoles of sodium per 135 ml dose.

WHAT LENOLAX IS USED FOR

LENOLAX is used for relief of occasional constipation.

BEFORE YOU RECEIVE LENOLAX

You should not be given LENOLAX

If you are allergic (hypersensitive) to sodium phosphate, sodium acid phosphate or any other ingredients contained in LENOLAX.

- If you have a severe kidney disease.
- If you have too much phosphate in your blood (hyperphosphataemia).
- If you have a condition whereby your large intestine has widened (megacolon).

Take special care with LENOLAX

- **Do not use more than one dose of LENOLAX within a 24 hour period.**
- If the patient is an infant, a child or an elderly person, or suffers from kidney disease or heart failure LENOLAX may cause electrolyte disturbances. Severe electrolyte disturbances may result in involuntary contraction of muscles and even death. Increased phosphate levels may cause an increase in the amount of calcium deposited in the kidneys which could result in kidney failure. Discuss this with your doctor or pharmacist before using LENOLAX.
- You should drink sufficient quantities of clear fluids while using LENOLAX.
- Do not use LENOLAX if you are dehydrated.
- Do not use LENOLAX you are nauseous, vomiting or have abdominal pain.
- Use of LENOLAX regularly and for long periods may result in laxative dependence and

loss of your normal gut function.

- LENOLAX should not be used for longer than a week (7 days) except on the advice of a doctor.
- If you have noticed a sudden change in your bowel movements that has lasted for more than 2 weeks, consult a doctor before using LENOLAX.
- If you have rectal bleeding or do not have a bowel movement after using a LENOLAX, stop using it and consult a doctor as this may be a sign of a serious condition.
- If you are on a low salt diet, have kidney disease, or suffer from high blood pressure, do not use LENOLAX except under the supervision of a doctor.
- Tell your doctor if you have a condition of fluid accumulation in lungs, or have had serious metabolic abnormalities during pregnancy associated with high blood pressure, as your body may retain sodium and water which could result in swelling in certain parts of the body.

Pregnancy and breastfeeding

The safety of LENOLAX during pregnancy and whilst breastfeeding has not been established.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before using LENOLAX.

Driving and using machinery

LENOLAX is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that LENOLAX does not adversely affect your ability to do so safely (see POSSIBLE SIDE EFFECTS).

Using other medicines with LENOLAX

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

In particular tell your doctor if you are taking any of the following medicines:

Calcium supplements or calcium containing antacids.

- Diuretics, used for high blood pressure, heart failure, kidney and liver problems, and glaucoma.
- Medicines used for high blood pressure.
- Anti-inflammatory medicines such as aspirin, ibuprofen, and naproxen, used for pain and inflammation.

HOW TO USE LENOLAX

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

Do not use more than one dose of LENOLAX within a 24 hour period.

Always use LENOLAX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

LENOLAX generally produces bowel movement in 2 to 15 minutes.

Do not administer to children under 2 years of age unless directed by a doctor.

LENOLAX should only be administered rectally.

LENOLAX:

Adults and children 12 years of age and over: The contents of one (adult) bottle **(135 ml).**

LENOLAX PAEDIATRIC:

Children 2 to under 12 years of age: The contents of one (paediatric) bottle **(64 ml).**

Do not use more than one dose of LENOLAX within a 24 hour period.

May be used at room temperature or as directed by your doctor.

For best results lie on your left side with knees bent, or in knee-chest position. Remove cover from rectal tube by holding bottle at neck and lifting off. Lubricate tip of tube with suitable lubricant (petroleum jelly or other suitable substance). Insert tube in the rectum. Squeeze bottle gently until desired quantity has been given. You should remain in this position until the urge to evacuate is strong usually within 2 to 15 minutes.

If you have the impression that the effect of LENOLAX is too strong or too weak, tell your doctor or pharmacist.

If you use more LENOLAX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

POSSIBLE SIDE EFFECTS

LENOLAX can have side effects.

Not all side effects reported for LENOLAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LENOLAX, please consult your healthcare provider for advice.

- **If any of the following happens, stop receiving LENOLAX and tell your doctor**

immediately or go to the casualty department at your nearest hospital: Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

If you experience any of the above you may have had a serious allergic reaction to LENOLAX. You 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:

- Restlessness, weakness, thirst, reduced salivation and lacrimation, swollen tongue, flushing of the skin, fever, dizziness, headache, reduced urine production, low blood pressure, rapid heartbeat, delirium, abnormally rapid and deep breathing, or stopping to breathe, which are symptoms of hypernatremia (an excess of sodium).
- Drowsiness, abnormal heart rate, bloating, extreme fatigue, increased blood pressure, low back pain, muscle spasms/cramping, as these may be symptoms of a serious kidney condition referred to as acute phosphate nephropathy.

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

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- rectal bleeding, blistering, burning, itching or pain at the administration site.

The following side effects have been reported less frequently:

- nausea, vomiting, diarrhoea, abdominal pain
- hypocalcaemia (low serum calcium levels in the blood)
- hypernatraemia (electrolyte disturbance that is defined by an elevated sodium level in

the blood) (see section

If any of the following happens, stop receiving LENOLAX and tell your doctor immediately or go to the casualty department at your nearest hospital).

- Hyperphosphatemia (is an electrolyte disturbance in which there is an abnormally elevated level of phosphate in the blood).
- Ectopic calcification (is a pathologic deposition of calcium salts in tissues or bone growth in soft tissues).
- Hyperkalemia (a potassium level in your blood that's higher than normal).
- Hypokalemia (a low level of potassium in your blood).

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

STORING AND DISPOSING OF LENOLAX

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF LENOLAX

LENOLAX PAEDIATRIC (64 ml) is packed in translucent amber low density polyethylene round bottle with a low density polypropylene cap and a separate low density polyethylene screw on nozzle together with a polyvinyl chloride valve which fits into the nozzle.

LENOLAX (adult) (135 ml) is packed in translucent amber low density polyethylene round bottle with a low density polypropylene cap and a separate low density polyethylene screw on nozzle together with a polyvinyl chloride valve which fits into the nozzle.

Not all packs and packs sizes are necessarily marketed.

IDENTIFICATION OF LENOLAX

A clear, colourless aqueous solution, free of particulate matter.

REGISTRATION NUMBER

LENOLAX PAEDIATRIC: E/11.5/1982

LENOLAX: E/11.5/819

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

Tel: +27 11 239 6200 (Other)

DATE OF PUBLICATION

Dates of registration:

LENOLAX PAEDIATRIC: 14 November 1996

LENOLAX: 08 October 1996

Date of the most recent amendment to the patient information leaflet as approved by the

Authority: 02 June 2017

Botswana: S2 LENOLAX PAEDIATRIC: BOT0901533 LENOLAX: BOT0901534

Namibia: NS0 LENOLAX PAEDIATRIC: 04/11.5/0119 LENOLAX: 04/11.5/0118

ZA_LENOSOL_1706_01