1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

LENOLAX PAEDIATRIC (enema)

LENOLAX (enema)

COMPOSITION

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.

CATEGORY AND CLASS

A 11.5 Medicines acting on the gastrointestinal tract: Laxatives

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Sodium phosphate and sodium acid phosphate are saline laxatives. Their action results from osmotically medicated water retention, thus increasing stimulation of fluid secretion, thereby promoting peristalsis (bowel movements).

Pharmacokinetic properties

Colonic absorption is probably minimal, but it has been reported that asymptomatic hyperphosphataemia up to 2 to 3 times above normal phosphorus levels occurs in nearly 25 % of individuals with normal renal function after administration of ORAL sodium phosphate containing colonic preparations. Data for high volume (250 ml) and 133 ml sodium phosphate rectal solutions in healthy volunteers confirmed a transient increase in serum phosphate above the upper limit of normal in 30 % of subjects, with mean phosphorus levels falling after the 10-minute sample. Under normal conditions the greatest phosphorus absorption occurs in the small bowel which is never reached from rectal administration.

INDICATIONS

- Relief of occasional constipation.

CONTRAINDICATIONS

LENOLAX is contraindicated in patients with:

- Hypersensitivity to sodium phosphate, sodium acid phosphate or to any of the ingredients contained in LENOLAX (see COMPOSITION).
- Severely impaired renal function.
- Hyperphosphataemia.
- Megacolon as hypernatraemic dehydration may occur.

WARNINGS AND SPECIAL PRECAUTIONS

Hyperphosphataemia, accompanied by hypocalcaemia or other severe electrolyte disturbances and resulting in tetany and even death, has been reported after the use of phosphate enemas such as LENOLAX. Hyperphosphataemia may precipitate nephrocalcinosis, causing an acute phosphate nephropathy. Hyperphosphataemia and hypocalcaemia have occurred in children after the use of phosphate enemas, such as LENOLAX.

LENOLAX should not be used in patients with nausea, vomiting or abdominal pain.

Frequent or prolonged use of LENOLAX may result in dependence and loss of normal bowel function.

Severe dehydration and changes in the levels of serum electrolytes from taking more than one dose of sodium phosphate, as contained in LENOLAX, within a 24 hour period may result in serious adverse effects on organs, such as the kidneys and heart, and may result in death. These serum electrolytes include calcium, sodium, and phosphate. Serious harm can also occur with a single dose that is larger than recommended.

Some patients may be at higher risk for potential adverse events when the recommended dose of LENOLAX is exceeded. These patients include young children, patients older than 55 years, patients who are dehydrated, patients with kidney disease, bowel obstruction, or inflammation of the bowel, and patients who are using medicines that may affect kidney function. These medicines include diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs) and nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin,

ibuprofen, and naproxen.

Excessive use may cause hyperphosphataemia, which may lead to development of hypocalcaemia, and ectopic calcification due to precipitation of calcium phosphate.

LENOLAX should not be used in patients with a sudden change in bowel habits that has persisted for a period greater than 2 weeks.

LENOLAX should not be used in patients with rectal bleeding or failure to have a bowel movement after use of a laxative. This may indicate a serious condition and LENOLAX should be discontinued.

LENOLAX contains sodium (see COMPOSITION). Patients on a low salt diet, with kidney disease, or suffering from high blood pressure, should not use LENOLAX except under the supervision of a healthcare professional.

Sodium salts, such as contained in LENOLAX should be used cautiously in patients with cardiac failure, hypertension, and impaired renal function, peripheral and pulmonary oedema and in toxaemia of pregnancy.

LENOLAX may cause hypernatraemia. Sodium “excess” may take two forms. The first is a rise in extracellular concentration (hypernatraemia) and the second form is excessive sodium and water in the body without change in the extracellular concentration. Symptoms of hypernatraemia may include restlessness, weakness, thirst, recuced salivation and lachrymation, swollen tongue, flusing of the skin, pyrexia, dizziness, headache, oliguria, hypotension, tachycardia, delirium, hyperpnoea and respiratory arrest.

Retention of sodium and water may lead to the accumulation of extracellular fluid (oedema). This may affect the cerebral, pulmonary, or peripheral circulation. It is the consequence of heart failure, renal failure, increased adrenocortical activity, the administration of corticosteroids, or excessive administration of sodium after operation or injury (when there is a renal restriction on sodium excretion).

LENOLAX should not be administered to dehydrated patients.

When using LENOLAX, sufficient quantities of clear fluids should be taken.
LENOLAX should be avoided in patients with low serum calcium concentrations, as these may decrease further, and in patients with infected phosphate renal calculi.

LENOLAX should be avoided in patients with hyperkalaemia.

Effects on ability to drive and use machines
Patients should not drive, use machinery or perform any tasks that require concentration until they are certain that LENOLAX does not adversely affect their ability to do so safely (see SIDE EFFECTS).

INTERACTIONS
Hyperphosphataemia, hypocalcaemia, and hypernatraemia are more likely to occur with phosphate enemas such as LENOLAX or oral laxatives if these are given to patients receiving diuretics or other medicines that may affect serum electrolytes. The risk of ectopic calcification may be increased by concurrent use of calcium supplements or calcium-containing antacids.

The risk of hyperkalaemia is increased if potassium phosphates are given with medicines that can increase serum potassium concentrations.

LENOLAX should be used with caution in patients taking medicines that affect kidney function or perfusion, such as diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), and possibly non-steroidal anti-inflammatory medicines (NSAIDs) (see WARNINGS AND SPECIAL PRECAUTIONS).

HUMAN REPRODUCTION

The safety of LENOLAX in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Do not use more than one dose of LENOLAX within a 24 hour period (see WARNINGS AND SPECIAL PRECAUTIONS).

LENOLAX generally produces bowel movement in 2 to 15 minutes.

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

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).

LENOLAX may be used at room temperature or as directed by a healthcare professional. For best results place the patient on 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. The patient should remain in this position until urge to evacuate is strong usually within 2 to 15 minutes.

SIDE EFFECTS

Metabolism and nutrition disorders

Less frequent: Hyperphosphataemia, hypocalcaemia, ectopic calcification, hypernatraemia, dehydration, hyperkalaemia, hypokalaemia

Gastrointestinal system disorders

Less frequent: Nausea, vomiting, diarrhoea, abdominal pain

Renal and urinary disorders

Less frequent: Acute phosphate nephropathy

General disorders and administration site conditions

Frequent: Rectal irritation

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

See WARNINGS AND SPECIAL PRECAUTIONS and SIDE EFFECTS.

Treatment

Treatment is symptomatic and supportive.

If dehydration occurs then electrolyte replacement solution is necessary, or hospitalisation and intravenous hydration if patients are unable to drink an appropriate volume of fluid.

IDENTIFICATION

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

PRESENTATION

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 pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

LENOLAX PAEDIATRIC: E/11.5/1982

LENOLAX: E/11.5/819

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Dates of registration:

LENOLAX PAEDIATRIC: 14 November 1996

LENOLAX: 08 October 1996

Date of the most recent amendment to the professional information 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