

SUMMARY OF PRODUCT CHARACTERISTICS (SPCs)

1. Name of the medicinal Product

Kleen Enema

2. Qualitative and quantitative composition

Kleen Enema (120ml)

Each 120ml (delivered dose) contains:

Monobasic Sodium Phosphate USP.....19.2g

Dibasic Sodium Phosphate USP.....7.2g

(USP Specifications)

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Rectal Solution (Enema)

4. Clinical Particulars

4.1. Therapeutic Indications

For relief of constipation. Bowel cleaning before rectal examination, abdominal x-rays, pelvic and abdominal surgery, child birth etc.

4.2. Posology and method of administration

Kleen Enema 120ml

Adult: One bottle of 120 ml (delivered dose) or as directed by the physician. Kleen Enema produces evacuation within about 5 minutes after use. Effective for relief of constipation and cleanness of the lower bowel. To be used at room temperature.

Direction for use: Lie on left side with right knee bent, or lie in a knee - chest position with face and abdomen downwards and arms in a comfortable position. Both these positions make introduction of rectal nozzle tip easy. Administering enema: Remove protective shield covering the lubricated tip before use. Gently insert the nozzle tip into rectum with steady pressure with tip directed towards navel. Squeeze bottle until nearly all liquid is expelled. Now remove the tip from rectum. After squeezing, small quantity of liquid (15 ml or 1/2 oz) will remain in the bottle, it is not necessary to empty the bottle completely as bottle contains a little extra (about 15 ml) to deliver the necessary dose easily. Maintain

the body position till urge to evacuate is strong which takes about 2 to 5 minutes.

4.3. Contraindications

Do not use laxative products when nausea, vomiting or abdominal pain is present unless directed by a physician. If you notice a sudden change in bowel habits that persists over a period of 2 weeks, consult a physician. Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a physician. Laxative products should not be used longer than 1 week unless directed by a physician. As with any drug, if you are pregnant or nursing a baby, seek the advice of a healthcare professional before using this product.

4.4. Special warnings and precautions for use

Warnings:

Using more than one enema in 24 hours can be harmful. Do not use in patients with megacolon, gastrointestinal obstruction, imperforate anus or congestive heart failure. Use with caution in patients with impaired renal function or pre-existing electrolyte disturbances, or in patients on diuretics or other medications which may affect electrolyte levels or where colostomy exists. Since Kleen Enema contains sodium phosphates, there is a risk of elevated serum levels of sodium and phosphate and decreased levels of calcium and potassium, and consequently hypernatremia, hyperphosphatemia, hypocalcemia, hypokalemia and acidosis may occur. This is of particular concern in children with megacolon or any other condition where there is retention of enema solution.

Precautions:

Do not administer the 120 ml (delivered dose) adult size to children under 12 years of age. If after the enema solution is administered there is no return of liquid, contact a physician immediately, as dehydration could occur.

Pregnancy:

This laxative contains a large amount of sodium, which may have unwanted effects during pregnancy, such as higher blood pressure. If laxative have to be taken during pregnancy, consult the doctor for specific advice.

Breast Feeding:

Sodium phosphate may pass into breast milk; caution is advised. Consult the doctor for specific advice

4.5. Interaction with other medicinal products and other forms of interaction

Use with caution in patients taking calcium channel blockers, diuretics, lithium treatment or other medications that might affect electrolyte levels as hyperphosphataemia, hypocalcaemia, hypokalaemia, hypernatraemic dehydration and acidosis may occur (see section 4.4).

No other sodium phosphate preparations including sodium phosphate oral solution or tablets should be given concomitantly (see section 4.3).

As hypernatraemia is associated with lower lithium levels, concomitant use of Cleen Ready-to-Use Enema and lithium therapy could lead to a fall in serum lithium levels with a lessening of effectiveness.

4.6. Fertility, pregnancy and lactation

Pregnancy:

This laxative contains a large amount of sodium, which may have unwanted effects during pregnancy, such as higher blood pressure. If laxative have to be taken during pregnancy, consult the doctor for specific advice.

Breast Feeding:

Sodium Phosphate may pass into breast milk; caution is advised. Consult the doctor for specific advice.

4.7. Effects on ability to drive and use machines

Monobasic Sodium Phosphate + Dibasic Sodium Phosphate has no influence on the ability to drive and use machines.

4.8. Undesirable effects

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur, they may need medical attention.

Less common adverse effects include rectal bleeding, blistering, burning, itching, or pain. Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, need medical attention if the following side effect continues or is bothersome.

Skin irritation surrounding rectal area

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

Reporting of Suspected Adverse Reaction:

Healthcare professionals are requested to report any suspected adverse reaction via Pharmacy and Poisons board, Pharmacovigilance Electronic

Reporting System (PvERS) <https://pv.pharmacyboardkenya.org> or National Regulatory Authorities.

4.9. Overdose

Over dosage or retention may lead to severe electrolyte disturbances, including hypernatremia, hyperphosphatemia, hypocalcemia, and hypokalemia, as well as dehydration and hypovolemia, with attendant signs and symptoms of these disturbances (such as metabolic acidosis, renal failure, and tetany). Certain severe electrolyte disturbances may lead to cardiac arrhythmia and death. The patient who has taken an overdose should be monitored carefully. Treatment of electrolyte imbalance may require immediate medical intervention with appropriate electrolyte and fluid replacement.

5. Pharmacological Properties

5.1. Pharmacodynamic Properties

Pharmacotherapeutic group: Osmotically acting laxatives

ATC Code: A06AG01

Kleen Enema is useful as a laxative in the relief of constipation, and as a bowel evacuant for a variety of diagnostic, surgical, and therapeutic indications. Kleen Enema provides thorough and safe cleansing action and induces complete emptying of the left colon usually within 2 to 5 minutes without pain or spasm. Kleen Enema may be used for the relief of constipation; as a routine enema; preparation for rectal examination, during pregnancy and pre- and post natally; preoperative cleansing and general postoperative care; to help in relieve of fecal or barium impaction.

5.2. Pharmacokinetic Properties

Colonic absorption is probably minimal, but it has been reported that asymptomatic hyperphosphataemia up to 2–3 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 rectal solutions have been generated by a small, open-label, healthy volunteer company sponsored study which looked at both 250ml (high volume) and 133ml sodium phosphate enemas. This study 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.

5.3. Preclinical Safety Data

No preclinical safety studies have been performed.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium benzoate

De-ionized water

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

36 months

6.4 Special precautions for storage

Store in a dry place at temperature below 30°C.

Keep out of the reach of children.

6.5 Nature and contents of container

Pack of 120ml (delivered dose):

Plastic LDPE clear bottle (135ml) with Nozzle assembly composed of Nozzle (cylindrical flexible rubber), Nozzle Cover with lock (HDPE), Cap (HDPE) and Wad (Flexible rubber with 13mm slit) which is further packed in a bleach board single carton.

7. Marketing Authorization Holder

Nabiqasim Industries (Pvt.) Ltd. 17/24, Korangi Industrial Area,
Korangi Karachi – Pakistan

8. Marketing Authorisation Number(s)

H2010/15773/211

9. Date of first authorization / renewal of the authorization

15/06/2026

10. Date of revision of the test

16/06/2026

