

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

E.S. Enema 161 mg/mL + 59 mg/mL Rectal Solution

For Children

Low density polyethylene bottles contain 67.5 mL of solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Drug substances:

	59 mL administration dose
Sodium dihydrogen phosphate	9.5 g
Disodium hydrogen phosphate	3.5 g

Excipients:

Methyl Paraben Sodium

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Rectal solution (Enema).

Transparent, colorless, odorless, precipitation and turbidity-free solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is used for the treatment of temporary constipation and for bowel cleansing before and after colon surgery near the rectum, before and after birth, before proctoscopy, sigmoidoscopy or colonoscopy and before radiology examinations.

4.2 Posology and method of administration

Posology/ Administration frequency and duration:

Unless otherwise recommended by the doctor, not more than once a day,

For children between 5 and 12 years old: Up to 67.5 mL per day (administration dose 59 mL) (1 bottle).

Children between 3 and 5 years: Up to 33.75 mL per day (administration dose 29.5 mL) (1/2 bottle).

It is not used in children under 3 years old.

Method of Administration:

For rectal use.

Both knees are bent. Lie to the left sideways leaning on the arms. The white protective cover is removed.

With constant pressure, the tip top of the enema is slowly inserted into the rectum and injected.

The bottle is squeezed until all the contents are finished. When the procedure is over, the tip is removed from the rectum.

If resistance is encountered, use is stopped. Enema made by force can cause injuries. Generally 2-5 minutes is enough to achieve the desired effect. If the effect is delayed, do not continue the next use, consult your doctor.

The use of rectal enema for transient constipation is only used for short-term relief.

Additional information on specific populations

Renal / hepatic impairment: It should be used with caution in patients with impaired renal function. Dosage and administration are the same as for adults. It is not used in patients on low salt diet, with renal failure, congestive heart failure and patients with impaired electrolyte balance.

Pediatric population: A maximum of one bottle per day is used in children between the ages of 5 and 12, and a maximum of half a bottle per day in children between the ages of 3 and 5. It must not be used in children under 3 years old.

Geriatric population: For children. People over the age of 65 should pay particular attention to the advice given in later chapters. It should be used with caution in the elderly.

4.3 Contraindications

It must not be used in the following cases.

- For children under the age of 3,
- Hypersensitivity to any of the active substances or excipients.

It is not used in the following diseases.

- Congestive heart failure

- Conditions that cause a decrease in bowel movements
 - Known or suspected intestinal obstruction
 - Paralytic ileus
 - Anorectal constriction (stenosis)
 - Imperforate anus
 - Megacolon (congenital or acquired)
 - Hirschsprung disease
- Undiagnosed gastrointestinal pathology
 - Appendicitis symptoms, intestinal perforation, active inflammatory bowel disease
 - Undiagnosed rectal bleeding
- Dehydration and generally in all cases where the absorption capacity is increased or the elimination capacity is decreased

4.4 Special warnings and precautions for use

It should be used with caution in patients with poor body, elderly, uncontrolled arterial hypertension, uncontrolled ascites, heart disease, changes in the rectal mucosa (ulcers, fissures), colostomy, pre-existing electrolyte disturbances. Hypocalcemia, hypokalemia, hyperphosphatemia, hyponatremia and acidosis may occur. Hyperphosphatemia may be encountered in patients with suspected electrolyte disturbance. Electrolyte levels should be monitored before and after use for E.S. ENEMA FOR CHILDREN.

It should be used with caution in patients with abnormal kidney function. It must not be used in children under 3 years old.

It should not be used when there is nausea, abdominal pain, vomiting unless recommended by the doctor.

Patients should be warned that they will pass watery stools and should be encouraged to drink plenty of fluids to help prevent dehydration.

Repetitive and prolonged use is not recommended as it can make a habit. It should not be used for more than two weeks unless recommended by a doctor.

When there is rectal bleeding or bowel evacuation disorder (discharge occurs within 5 minutes after administration), it may indicate a serious health problem. Stop use and consult a doctor.

E.S. ENEMA FOR CHILDREN should be administered following the patient information leaflet (see Section 4.2.)

Patients should be warned to stop the administration if resistance is felt, since the administration will cause local damage.

Keep all medicines out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

It should be used with caution in combination with calcium channel blockers, diuretics, lithium therapy or other drugs that can affect electrolyte levels. Because hyperphosphatemia, hypocalcemia, hypokalemia, hypernatremic dehydration and acidosis may occur.

Since hypernatremia is associated with low lithium levels, concurrent administration of lithium therapy with E.S. ENEMA FOR CHILDREN may result in a decrease in serum lithium levels and treatment efficacy.

4.6 Pregnancy and lactation

ES ENEMA FOR CHILDREN is used for children.

General advice

Pregnancy category:C

Women with childbearing potential / Contraception:

There are insufficient data on its use in women of childbearing potential. Women of childbearing potential should use effective contraception throughout the treatment period.

Pregnancy

Available data are not sufficient to measure fetal malformations or other possible toxic effects when administered during pregnancy. E.S. ENEMA FOR CHILDREN should be used in the birth and postnatal period only with the advice of a doctor.

Lactation

It is unknown whether E.S. ENEMA FOR CHILDREN is excreted in human milk. Since sodium phosphate can pass into human milk, it is recommended that E.S. ENEMA FOR CHILDREN is milked for 24 hours after use.

Women must not breastfeed their babies for 24 hours after using E.S. ENEMA FOR CHILDREN.

Reproductive ability / Fertility

Since a pregnancy has not yet occurred, no side effects have been observed in the reproductive ability and fertility period.

4.7 Effects on ability to drive and use machines

Not valid.

4.8 Undesirable effects

Side effects seen were classified according to the following frequencies with the MedDRA V8.0 system:

Very common ($\geq 1/10$), Common ($\geq 1/100$ to $< 1/10$), Uncommon ($\geq 1/1,000$ to $< 1/100$), Rare ($\geq 1/10,000$ to $< 1/1,000$), Very rare ($< 1/10,000$), Unknown (cannot be estimated from the available data)

Immune system disorders:

Not known: Hypersensitivity reactions (itching, urticarial etc.)

Metabolism and nutrition disorders:

Not known: Dehydration, hyperphosphatemia, hypocalcemia, hypokalaemia, hypernatremia, metabolic acidosis

Gastrointestinal diseases:

Very common: Nausea

Common: Abdominal pain, diarrhea, abdominal distension, vomiting, gastrointestinal pain

Not known: Anal itching

General disorders and administration site conditions:

Not known: Chills, rectal irritation, blistering, pricking, itching, pain

Reporting of suspected adverse reactions

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

4.9 Overdose

It may cause death in patients with gastrointestinal obstruction in case of overdose or retention.

Overdose or involvement may cause hyperphosphatemia, hypocalcemia, hypernatremia, hypernatremic dehydration, acidosis and tetany.

Toxic effects can be easily eliminated by rehydration. In severe cases, the supply of calcium and magnesium salts (10% calcium gluconate) to correct the electrolyte level, encouragement of exogenous phosphate removal and subsequent dialysis may be envisaged.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Locally effective laxative

ATC code: A06AG01

E.S. ENEMA FOR CHILDREN is a rectally administered saline laxative. The lower intestinal fluid accumulation produces dissecting fluid and supports the evacuation of only the sigmoid rectum and the partial or descending colon and all peristalsis and bowel movements.

5.2 Pharmacokinetic properties

General Particulars

Asymptomatic hyperphosphatemia with phosphorus levels 2-3 times higher than normal phosphorus levels has been reported in approximately 25% of individuals with normal renal function after oral intake of colonic preparations containing sodium phosphate. Rectal solution data were analyzed with 250 mL (high volume) and 66.6 mL sodium phosphate enema in a study with small, open-labeled healthy volunteers sponsored by the company. This study confirms the transitory increase in serum phosphate, which is above the upper normal level in 30% of subjects, with mean phosphorus levels falling after 10 minutes of sample. Under normal conditions, most phosphorus absorption occurs in the small intestine, which cannot be reached by rectal administration.

It is locally effective. Since it is not absorbable, it does not show pharmacokinetic properties.

Absorption:

It has no absorption.

Distribution:

It is locally effective.

Biotransformation:

Biotransformation is not expected due to its local effect.

Elimination:

Does not undergo any elimination.

5.3 Preclinical safety data

Preclinical safety studies have not been conducted.

6. Pharmaceutical particulars

6.1 List of excipients

Substances in its composition

Methyl Paraben Sodium

Deionized water

Nozzle lubricant: white soft paraffin

6.2 Incompatibilities

Not reported.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Keep at room temperature below 25 ° C.

Do not freeze.

6.5 Nature and contents of container

Ready-to-use E.S. ENEMA FOR CHILDREN is presented in a squeeze bottle containing 67.5 mL of solution with LDPE, which is used once. The soft, comfortable and pre-lubricated end cap and cover are made of LDPE.

6.6 Special precautions for disposal

The outer packaging is recyclable since it is cardboard box. No special precaution is required.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER

2014/336

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17.04.2014

Date of latest renewal:

10. DATE OF REVISION OF THE TEXT

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