

## 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**

HAYER FARMA İlaç A.Ş.

Akbaba Mah. Maraş Cad. No:52/2/1 34820

Beykoz / İSTANBUL/TURKEY

Phone: 0216 324 38 38

Fax: 0216 317 04 98

**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**

-



MARKETING AUTHORIZATION HOLDER:

HAYER FARMA İLAÇ A.Ş.

MANUFACTURING SITE:

OSEL İLAÇ SAN.VE TİC. A.Ş.

## PATIENT INFORMATION LEAFLET

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

#### Administered via rectal for adults

- **Active Ingredients:**

	Every 118 mL administration dose	Every 177 mL administration dose
Sodium dihydrogen phosphate	19 g	28.5 g
Disodium hydrogen phosphate	7 g	10.5 g

- **Excipients:**

Methyl paraben sodium, deionized water

Nozzle lubricant: White soft paraffin

***Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.***

- *Keep this patient information leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

#### **What is in this leaflet:**

##### **1. What E.S. ENEMA FOR ADULTS is and what it is used for?**

##### **2. What you need to know before you use E.S. ENEMA FOR ADULTS**

##### **3. How to use E.S. ENEMA FOR ADULTS?**

##### **4. What are the possible side effects?**

##### **5. How to store E.S. ENEMA FOR ADULTS**

##### **1. What E.S. ENEMA FOR ADULTS is and what it is used for?**

- E.S. ENEMA FOR ADULTS is used to relieve temporary constipation or to cleanse the bowel.
- E.S. ENEMA FOR ADULTS is a bowel cleanser that increases the amount of water in the stool and thus helps to excrete and cleanse the bowel.
- E.S. ENEMA FOR ADULTS contains saline laxative. Saline laxatives provide water retention in the bowel (sigmoid colon). As a result of this effect, the bowel is stimulated within 2 to 5 minutes and excretion takes place.
- In endoscopy, bowel surgery and X-ray examinations where temporary constipation or intestinal cleansing is required,
- It is used to clean / evacuate the bowel before rectal examination or control procedures.

- Soft and flexible nozzle provides a comfortable administration in a short time as it contains lubricant.
- Latex is not used in any E.S. ENEMA product.
- It is used in adults and children over 12 years old.

## **2. What you need to know before you use E.S. ENEMA FOR ADULTS**

Do not administer an adult dose of 135 mL for children under the age of 12. (For children under the age of 12, there is a dose of 67.5 ml, which corresponds to half the adult dose.) With the administration, the excretion of stool will be watery, so plenty of fluids should be taken to prevent fluid loss in the body.

It may be harmful to take more than one bottle of E.S. ENEMA FOR ADULTS within 24 hours. Do not use laxative products for longer than two weeks, unless recommended by your doctor.

In case of oral ingestion, seek medical help immediately or contact a poison control center. Rectal discomfort or a burning sensation may occur.

### **DO NOT use E.S. ENEMA FOR ADULTS in the following situations.**

- If you are allergic to any of the active substance or excipients in E.S. ENEMA FOR ADULTS
- If you have excessive enlargement of your large bowel (megacolon)
- If there is a narrowing or defect in the anus or rectum
- If there is an obstruction in the large intestine (Hirschsprung disease)
- If there is a suspected intestinal obstruction
- If there is a blockage in the intestines or a disorder in normal bowel movements
- Under 3 years old

If it has been indicated by your doctor that you have or may have even one of the following conditions:

- Appendicitis
- Perforated / damaged or obstructed bowel
- Inflammatory bowel disease
- Rectal bleeding diagnosis
- If there is a problem with the heart pumping blood to the whole body (congestive heart failure)
- Nausea or thirst
- Abdominal pain

### **USE E.S. ENEMA FOR ADULTS CAREFULLY in the following situations.**

- If you are elderly or weak
- If you have uncontrolled blood pressure
- If you have heart or kidney disease
- If you have water accumulation in the stomach
- If you have rectal ulcers or cracks
- If you have had colostomy surgery

- Changes in salt and water levels in your body (electrolyte disturbances)

If these warnings are valid for you, even at any time in the past, please consult your doctor.

### **Using USE E.S. ENEMA FOR ADULTS with food and drink:**

There is no interaction with food and drinks in terms of administration method.

### **Pregnancy**

*Consult your doctor or your pharmacist before using the drug.*

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

*If you notice you are pregnant during treatment, consult your doctor or pharmacist immediately.*

### **Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

Since sodium phosphate can pass into breast milk, the milk formed within 24 hours after E.S. ENEMA FOR ADULTS intake should be expelled. Breastfeeding is recommended 24 hours after this procedure.

### **Driving and using machines**

E.S. ENEMA FOR ADULTS has no direct effect on the driving and using machines. Dizziness may occur due to dehydration. After using the medicine, you must be near the toilet.

### **Important information about some excipients found in the composition of E.S. ENEMA FOR ADULTS**

#### **Use with other medicines**

If you are currently using any prescription or non-prescription medication of the following type or you have used it recently, please inform your doctor or pharmacist about them:

- High blood pressure or heart disease medications (calcium channel blockers)
- Bladder emptying drugs (diuretics)
- Some medicines for mental distress (lithium)
- Medicines that can dehydrate the body or medicines that can alter the salt level (potassium, sodium, phosphate, or water) in the body, known as electrolyte balance

*If you are currently using any prescription or non-prescription medication of the following type or you have used it recently, please inform your doctor or pharmacist about them.*

### 3. How to use E.S. ENEMA FOR ADULTS?

- **Instructions for appropriate use and dose/administration frequency:**

It is only taken rectally (anally). Do not take it by oral ingestion.

In adults and children over 12 years of age, a maximum of one bottle per day is used, unless otherwise indicated by the physician.

Before starting to inject, remove the white protective cap.

Unless otherwise recommended by your doctor, E.S. ENEMA FOR ADULTS should not be used for longer than 14 days.

If there is resistance, use is discontinued. Strain of E.S. ENEMA FOR ADULTS can cause damage.

**Note:** There is no need to completely empty the bottle. For effective use, the amount in the bottle is more than the therapeutic dose. After use, some liquid will increase in the bottle. The position is maintained until it is completely emptied. (Usually 2 - 5 minutes)

- **Route and Method of administration:**

Left side position:

Lie on the left. Knees bend to the right and arms swing freely.



Knee-chest position:

Kneel down. The head is tilted down and the chest is moved forward. The left side of the face is brought closer to the surface and placed comfortably on the left arm.



1. Choose the appropriate one of the above two positions (left lateral position or knee-chest position).
2. Remove the white protective cover. Holding the bottle upright, grasp the cap of the corrugated bottle with your finger. With the other hand, gently pull off the protective cover.
3. Gently insert the tip of the vial into the rectum with steady pressure, aiming at the anus center.
4. **Do not use excessive force while the tip is inserted into the rectum as it may cause damage.**
5. If the bowel emptying movement is given to the anus (providing a stool movement), the tip is placed more easily. This movement allows the muscles around the anus to relax.
6. Squeeze the bottle until almost all of the liquid is drained.
7. Remove the tip from the rectum and hold your position until the bowel emptying movement begins (normally 2-5 minutes).

**Various age groups:**

Pediatric Use: For children aged 3-12, "E.S. ENEMA FOR CHILDREN" form is available. (E.S. ENEMA FOR ADULTS dose for adults is 135 mL, for children, the dose is 67.5 ml, which is equivalent to half of this dose.)

## **Special use cases:**

### **Renal/Hepatic Impairment:**

If you have liver dysfunction, if you are on a salt-banned diet or if you have kidney disease, do not use unless your doctor recommends it.

In elderly and sluggish patients and uncontrolled arterial hypertension, abdominal water accumulation, heart disease, intestinal lining (rectal mucosa) changes (e.g. ulcer, fissure) with colostomy or persistent low calcium level (hypocalcemia), blood potassium level It should be used with caution in people with electrolyte disorders such as low blood pressure (hypokalemia), high phosphate level in the blood (hyperphosphatemia), increased sodium level in the blood (hypernatremia), and especially in diabetes mellitus (acidosis).

*Talk to your doctor or pharmacist if you have the impression that the effect of E.S. ENEMA FOR ADULTS is too strong or weak.*

### **If you have used more E.S. ENEMA than you should**

If more than necessary amount of E.S. ENEMA FOR ADULTS is taken, seek professional help or contact a health center.

Overdose or retention; Increased sodium level in the blood (hypernatremia), increased blood phosphate level (hyperphosphatemia), decreased calcium level (hypocalcemia) and decreased potassium level in the blood (hypokalemia), such as salt and mineral levels (electrolytes), may cause impairment in the body. In addition to these, dehydration (dehydration) and hypovolemia (decrease in blood volume) may occur with some signs and symptoms (eg metabolic acidosis, renal failure and tetany). Some severe electrolyte disturbances can lead to heart rhythm disturbances (cardiac arrhythmia) and death. If you have overdosed, you should be followed carefully. **Electrolyte disturbance treatment requires urgent medical attention with appropriate electrolyte and fluid replacement.**

*Talk to a doctor or pharmacist if you have used more than you should use from E.S. ENEMA FOR ADULTS.*

### **If you forget to use E.S. ENEMA FOR ADULTS**

If you forget to use E.S. ENEMA, use it again in normal doses.

*Do not take a double dose to make up for forgotten doses.*

### **Effects which may occur when treatment with E.S. ENEMA FOR ADULTS is concluded**

There is no data on any effect when treatment is terminated.

## **4. What are the possible side effects?**

As with all medicines, there may be side effects in people who are sensitive to the ingredients of E.S. ENEMA FOR ADULTS.

The incidence of undesirable effects seen with E.S. ENEMA FOR ADULTS is unknown (cannot be estimated from the available data).

**Stop using E.S. ENEMA FOR ADULTS if any of the following occur, and immediately notify your physician or consult the emergency department of your nearest hospital:**

- Rectal bleeding (bloody stool or blood coming from the bowel)
- Severe sudden allergic reaction (rash, itching, swelling of the face and lips, or swelling of the mouth and throat to make swallowing or breathing difficult) with difficulty breathing and feeling faint or dizzy
- No bowel movement or stool excretion after E.S. ENEMA FOR ADULTS is given.

These are all very serious side effects.

If you have one of these, you may need urgent medical attention or hospitalization.

**If you notice any of the following, immediately report to your doctor or contact the emergency department of your nearest hospital:**

- Dehydration (excessive dehydration of the body)
- Allergic reactions (itching, hives (urticaria))
- Muscle twitching or sudden contractions due to changes in the amount of electrolytes (salts) in the blood.
- Abdominal pain or bloating due to gas accumulation in the intestines
- Vomiting or nausea
- Itching or burning in the anal area
- Formation of liquid-filled blisters on the skin
- Diarrhea
- Tremor accompanied by a feeling of cold
- Pricking
- Increased levels of phosphate in the blood (hyperphosphatemia)
- Low calcium levels (hypocalcemia)
- Low levels of potassium in the blood (hypokalaemia)
- Increased sodium level in the blood (hypernatremia)
- Disruption of acid excretion in the body (metabolic acidosis)

*If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.*

### **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.

### **5. How to store E.S. ENEMA FOR ADULTS**

*Keep E.S. ENEMA FOR ADULTS out of the reach and sight of children and within its packaging*

Do not buy cut or opened packages.

Store at room temperature below 25°C.

Do not freeze.

**Use in compliance with the expiry date.**

*Do not use E.S. ENEMA FOR ADULTS after the expiry date which is stated on the packaging.*

***Marketing Authorization Holder:***

HAVER FARMA İlaç A.Ş.  
Akbaba Mah. Maraş Cad. No:52/2/1 34820  
Beykoz / İSTANBUL  
Tel: 0216 324 38 38  
Fax: 0216 317 04 98

***Manufacturing Site:***

OSEL İlaç San. ve Tic. A.Ş.  
Akbaba Mah. Maraş Cad. No.:52 Beykoz / İstanbul

This patient information leaflet approved in 02/02/2015



THE FOLLOWING INFORMATION IS FOR THE HEALTH PERSONNEL WHO APPLY THIS MEDICINE:

Congenital megacolon should not be used in people with intestinal obstruction, imperforate anus, or congestive heart disease. It should be used with caution in people who have had renal impairment, pre-existing electrolyte disturbances, or who have undergone colostomy or use diuretics or who are taking medications such as hypocalcemia, hyperphosphatemia, hypernatremia, or acidosis.

Since E.S. ENEMA has adult and child forms, prescription should be done accordingly.

## PATIENT INFORMATION LEAFLET

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

**Administered via rectal for children.**

- ***Active Ingredients:***

An administration dose of 59 mL contains;

Sodium dihydrogen phosphate 9.5 g

Disodium hydrogen phosphate 3.5 g

- ***Excipients:***

Methylparaben sodium, deionized water

Nozzle lubricant: White soft paraffin

**Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.**

- *Keep this patient information leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

### **What is in this leaflet:**

- 1. What E.S. ENEMA FOR CHILDREN is and what it is used for?***
- 2. What you need to know before you use E.S. ENEMA FOR CHILDREN***
- 3. How to use E.S. ENEMA FOR CHILDREN?***
- 4. What are the possible side effects?***
- 5. How to store E.S. ENEMA FOR CHILDREN.***

#### **1. What E.S. ENEMA FOR CHILDREN is and what it is used for?**

- E.S. ENEMA FOR CHILDREN is used to relieve temporary constipation or to cleanse the bowel.
- E.S. ENEMA FOR CHILDREN is a bowel cleanser that increases the amount of water in the stool and thus helps to excrete and cleanse the bowel.
- E.S. ENEMA FOR CHILDREN contains saline laxative. Saline laxatives provide water retention in the bowel (sigmoid colon). As a result of this effect, the bowel is stimulated within 2 to 5 minutes and excretion takes place.
- In endoscopy, bowel surgery and X-ray examinations where temporary constipation or intestinal cleansing is required,

- It is used to clean / evacuate the bowel before rectal examination or control procedures.
- Soft and flexible nozzle provides a comfortable administration in a short time as it contains lubricant.
- Latex is not used in any E.S. ENEMA product.
- It is used in children between 3 and 5 years old.
- It is used in children between 5 and 12 years old.

## **2. What you need to know before you use E.S. ENEMA FOR CHILDREN**

With the administration, the excretion of stool will be watery, so plenty of fluids should be taken to prevent fluid loss in the body.

It may be harmful to take more than one bottle of E.S. ENEMA within 24 hours. Do not use laxative products for longer than two weeks, unless recommended by your doctor.

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

In case of oral ingestion, seek medical help immediately or contact a poison control center.

Rectal discomfort or a burning sensation may occur.

### **DO NOT use E.S. ENEMA FOR CHILDREN in the following situations.**

- If you are allergic to any of the active substance or excipients in E.S. ENEMA FOR CHILDREN
- If you have excessive enlargement of your large bowel (megacolon)
- If there is a narrowing or defect in the anus or rectum
- If there is an obstruction in the large intestine (Hirschsprung disease)
- If there is a suspected digestive system obstruction
- If there is a blockage in the digestive system or defects in normal bowel movements

If it has been indicated by your doctor that you have or may have even one of the following conditions:

- Appendicitis
- Wimble / damaged or clogged digestive system
- Inflammatory bowel disease
- Rectal bleeding
- If there is a problem with the heart pumping blood to the whole body (congestive heart failure)
- Nausea or thirst
- Abdominal pain
- Under 3 years old

### **USE E.S. ENEMA FOR CHILDREN CAREFULLY in the following situations.**

- Have uncontrolled blood pressure
- If you have heart or kidney disease
- If you have water accumulation in the stomach
- If you have rectal ulcers or cracks
- If you have had colostomy surgery
- Changes in salt levels in your body (electrolyte disturbances)

If these warnings are valid for you, even at any time in the past, please consult your doctor.

### **Using USE E.S. ENEMA FOR CHILDREN with food and drink:**

There is no interaction with food and drinks in terms of administration method.

## **Pregnancy**

*Consult your doctor or your pharmacist before using the drug.*

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

*If you notice you are pregnant during treatment, consult your doctor or pharmacist immediately.*

## **Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

Since sodium phosphate can pass into breast milk, the milk formed within 24 hours after E.S. ENEMA intake should be expelled. Breastfeeding is recommended 24 hours after this procedure.

## **Driving and using machines**

E.S. ENEMA has no direct effect on the driving and using machines. Dizziness may occur due to dehydration. After using the medicine, you must be near the toilet.

## **Important information about some excipients found in the composition of E.S. ENEMA FOR CHILDREN**

### **Use with other medicines:**

If you are currently using any prescription or non-prescription medication of the following type or you have used it recently, please inform your doctor or pharmacist about them:

- High blood pressure or heart disease medications (calcium channel blockers)
- Bladder emptying drugs (diuretics)
- Some medicines for mental distress (lithium)
- Medicines that can dehydrate the body or medicines that can alter the salt level (potassium, sodium, phosphate, or water) in the body, known as electrolyte balance

*If you are currently using any prescription or non-prescription medication of the following type or you have used it recently, please inform your doctor or pharmacist about them.*

## **3. How to use E.S. ENEMA FOR CHILDREN?**

### **• Instructions for appropriate use and dose/administration frequency:**

It is only taken rectally (anally).

Unless otherwise specified by the physician;

No more than one bottle per day for children between the ages of 5 and 12,

A maximum of half a bottle per day is used in children aged 3 to 5 years.

Before starting to inject, remove the white protective cap.

Unless otherwise recommended by your doctor, E.S. ENEMA FOR CHILDREN should not be used for longer than 14 days.

If there is resistance, use is discontinued. Force of Enema can cause damage.

**Note:** There is no need to completely empty the bottle. For effective use, the amount in the bottle is more than the therapeutic dose. After use, some liquid will increase in the bottle. The position is maintained until it is completely emptied. (Usually 2 - 5 minutes)

- **Route and Method of administration:**

Left side position:

Lie on the left. Knees bend to the right and arms swing freely.



Knee-chest position:

Kneel down. The head is tilted down and the chest is moved forward. The left side of the face is brought closer to the surface and placed comfortably on the left arm.



1. Choose the appropriate one of the above two positions (left lateral position or knee-chest position).
  2. Remove the white protective cover. Holding the bottle upright, grasp the cap of the corrugated bottle with your finger. With the other hand, gently pull off the protective cover.
  3. Gently insert the tip of the vial into the rectum with steady pressure, aiming at the anus center.
  4. **Do not use excessive force while the tip is inserted into the rectum as it may cause damage.**
  5. If the bowel emptying movement is given to the anus (providing a stool movement), the tip is placed more easily. This movement allows the muscles around the anus to relax.
  6. Squeeze the bottle until almost all of the liquid is drained.
  7. Remove the tip from the rectum and hold your position until the bowel emptying movement begins (normally 2-5 minutes).
- **Special use cases:**

**Renal/Hepatic Impairment:**

If you have liver dysfunction, if you are on a salt-banned diet or if you have kidney disease, do not use unless your doctor recommends it.

In addition, uncontrolled arterial hypertension, accumulation of water in the abdomen, heart disease, changes in the intestinal lining (rectal mucosa) (e.g. ulcer, fissure) with colostomy or chronic low calcium level (hypocalcemia), low potassium level in the blood (hypokalemia) It should be used with caution in people with electrolyte disorders such as high phosphate level in the blood (hyperphosphatemia), increased sodium level in the blood (hypernatremia), and especially in diabetes mellitus with acidosis.

*Talk to your doctor or pharmacist if you have the impression that the effect of E.S. ENEMA FOR CHILDREN is too strong or weak.*

**If you have used more E.S. ENEMA FOR CHILDREN than you should**

If more than necessary amount of E.S. ENEMA FOR CHILDREN is taken, seek professional help or contact a health center.

Overdose or retention; Increased sodium level in the blood (hypernatremia), increased blood phosphate level (hyperphosphatemia), decreased calcium level (hypocalcemia) and decreased potassium level in the blood (hypokalemia), such as salt and mineral levels (electrolytes), may cause impairment in the body. In addition to these, dehydration (dehydration) and hypovolemia (decrease in blood volume) may occur with some signs and symptoms (eg metabolic acidosis, renal failure and tetany). Some severe electrolyte disturbances can lead to heart rhythm disturbances (cardiac arrhythmia) and death. If overdose is taken, careful monitoring is required. **Electrolyte disturbance treatment requires urgent medical attention with appropriate electrolyte and fluid replacement.**

*Talk to a doctor or pharmacist if you have used more than you should use from E.S. ENEMA FOR ADULTS.*

**If you forget to use E.S. ENEMA FOR CHILDREN**

If you forget to use E.S. ENEMA CHILDREN, use it again in normal doses.

*Do not take a double dose to make up for forgotten doses.*

**Effects which may occur when treatment with E.S. ENEMA FOR CHILDREN is concluded**

There is no data on any effect when treatment is terminated.

**4. What are the possible side effects?**

As with all medicines, there may be side effects in people who are sensitive to the ingredients of E.S. ENEMA FOR CHILDREN.

The incidence of undesirable effects seen with E.S. ENEMA FOR CHILDREN is unknown (cannot be estimated from the available data).

**Stop using E.S. ENEMA FOR CHILDREN if any of the following occur, and immediately notify your physician or consult the emergency department of your nearest hospital:**

- Rectal bleeding (bloody stool or blood coming from the bowel)
- Severe sudden allergic reaction (rash, itching, swelling of the face and lips, or swelling of the mouth and throat to make swallowing or breathing difficult) with difficulty breathing and feeling faint or dizzy.
- No bowel movement or stool excretion after E.S. ENEMA FOR CHILDREN is given.

These are all very serious side effects.

If you have one of these, you may need urgent medical attention or hospitalization.

**If you notice any of the following, immediately report to your doctor or contact the emergency department of your nearest hospital:**

E.S. ENEMA should be used as specified in the application route and method. If resistance is encountered, use should be discontinued.

In case of oral ingestion, seek medical help immediately or contact a poison control center. After administration,

- Rectal bleeding
  - If there is no movement in the bowel or fecal excretion after E.S. ENEMA is given, immediately inform your doctor or go to the nearest emergency department.
- All these are serious side effects. Emergency medical attention may be required.

**If you notice any of the following, tell your doctor:**

- Itching
- Hives (urticaria)
- More fluid loss than normal (dehydration)
- Increased levels of phosphate in the blood (hyperphosphatemia)
- Low calcium levels (hypocalcemia)
- Low levels of potassium in the blood (hypokalaemia)
- Increased sodium level in the blood (hypernatremia)
- Disruption of acid excretion in the body (metabolic acidosis)
- Nausea
- Vomiting
- Abdominal pain
- Abdominal bloating (abdominal distension)
- Diarrhea
- Ache
- Anal itching
- Chill
- Rectal irritation
- Swelling
- Pricking

These are mild side effects of ENEMA FOR CHILDREN.

*If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.*

**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.

**5. How to store E.S. ENEMA FOR CHILDREN.**

*Keep E.S. ENEMA FOR CHILDREN out of the reach and sight of children and within its packaging.*

Do not buy cut or opened packages.

Store at room temperature below 25°C.

Do not freeze.

**Use in compliance with the expiry date.**

*Do not use E.S. ENEMA FOR CHILDREN after the expiry date which is stated on the packaging.*

***Marketing Authorization Holder:***

Haver Farma İlaç A.Ş.  
Akbaba Mah. Maraş Cad. No:52/2/1 34820  
Beykoz / İSTANBUL  
Tel: 0216 324 38 38  
Fax: 0216 317 04 98

***Manufacturing Site:***

Osel İlaç San. ve Tic. A.Ş.  
Akbaba Mah. Maraş Cad. No.:52 Beykoz / İstanbul

This patient information leaflet approved in 02/02/2015



THE FOLLOWING INFORMATION IS FOR THE HEALTH PERSONNEL WHO APPLY THIS MEDICINE:

Congenital megacolon should not be used in people with intestinal obstruction, imperforate anus, or congestive heart disease. It should be used with caution in people who have had renal impairment, pre-existing electrolyte disturbances, or who have undergone colostomy or use diuretics or who are taking medications such as hypocalcemia, hyperphosphatemia, hypernatremia, or acidosis.

Since E.S. ENEMA has adult and child forms, prescription should be done accordingly.

MARKETING AUTHORIZATION HOLDER:  
HAVER FARMA İLAÇ A.Ş.

MANUFACTURING SITE:  
FARMAMAG AMBALAJ SAN.VE TİC. A.Ş.

## PATIENT INFORMATION LEAFLET

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

#### Administered via rectal for adults

- **Active Ingredients:**

	Every 118 mL administration dose	Every 177 mL administration dose
Sodium dihydrogen phosphate	19 g	28.5 g
Disodium hydrogen phosphate	7 g	10.5 g

- **Excipients:**

Methyl paraben sodium, deionized water

Nozzle lubricant: White soft paraffin

***Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.***

- *Keep this patient information leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

#### **What is in this leaflet:**

#### **6. What E.S. ENEMA FOR ADULTS is and what it is used for?**

#### **7. What you need to know before you use E.S. ENEMA FOR ADULTS**

#### **8. How to use E.S. ENEMA FOR ADULTS?**

#### **9. What are the possible side effects?**

#### **10. How to store E.S. ENEMA FOR ADULTS**

#### **4. What E.S. ENEMA FOR ADULTS is and what it is used for?**

- E.S. ENEMA FOR ADULTS is used to relieve temporary constipation or to cleanse the bowel.
- E.S. ENEMA FOR ADULTS is a bowel cleanser that increases the amount of water in the stool and thus helps to excrete and cleanse the bowel.
- E.S. ENEMA FOR ADULTS contains saline laxative. Saline laxatives provide water retention in the bowel (sigmoid colon). As a result of this effect, the bowel is stimulated within 2 to 5 minutes and excretion takes place.
- In endoscopy, bowel surgery and X-ray examinations where temporary constipation or intestinal cleansing is required,
- It is used to clean / evacuate the bowel before rectal examination or control procedures.

- Soft and flexible nozzle provides a comfortable administration in a short time as it contains lubricant.
- Latex is not used in any E.S. ENEMA product.
- It is used in adults and children over 12 years old.

## **5. What you need to know before you use E.S. ENEMA FOR ADULTS**

Do not administer an adult dose of 135 mL for children under the age of 12. (For children under the age of 12, there is a dose of 67.5 ml, which corresponds to half the adult dose.) With the administration, the excretion of stool will be watery, so plenty of fluids should be taken to prevent fluid loss in the body.

It may be harmful to take more than one bottle of E.S. ENEMA FOR ADULTS within 24 hours. Do not use laxative products for longer than two weeks, unless recommended by your doctor.

In case of oral ingestion, seek medical help immediately or contact a poison control center. Rectal discomfort or a burning sensation may occur.

### **DO NOT use E.S. ENEMA FOR ADULTS in the following situations.**

- If you are allergic to any of the active substance or excipients in E.S. ENEMA FOR ADULTS
- If you have excessive enlargement of your large bowel (megacolon)
- If there is a narrowing or defect in the anus or rectum
- If there is an obstruction in the large intestine (Hirschsprung disease)
- If there is a suspected intestinal obstruction
- If there is a blockage in the intestines or a disorder in normal bowel movements
- Under 3 years old

If it has been indicated by your doctor that you have or may have even one of the following conditions:

- Appendicitis
- Perforated / damaged or obstructed bowel
- Inflammatory bowel disease
- Rectal bleeding diagnosis
- If there is a problem with the heart pumping blood to the whole body (congestive heart failure)
- Nausea or thirst
- Abdominal pain

### **USE E.S. ENEMA FOR ADULTS CAREFULLY in the following situations.**

- If you are elderly or weak
- If you have uncontrolled blood pressure
- If you have heart or kidney disease
- If you have water accumulation in the stomach
- If you have rectal ulcers or cracks
- If you have had colostomy surgery

- Changes in salt and water levels in your body (electrolyte disturbances)

If these warnings are valid for you, even at any time in the past, please consult your doctor.

### **Using USE E.S. ENEMA FOR ADULTS with food and drink:**

There is no interaction with food and drinks in terms of administration method.

### **Pregnancy**

*Consult your doctor or your pharmacist before using the drug.*

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

*If you notice you are pregnant during treatment, consult your doctor or pharmacist immediately.*

### **Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

Since sodium phosphate can pass into breast milk, the milk formed within 24 hours after E.S. ENEMA FOR ADULTS intake should be expelled. Breastfeeding is recommended 24 hours after this procedure.

### **Driving and using machines**

E.S. ENEMA FOR ADULTS has no direct effect on the driving and using machines. Dizziness may occur due to dehydration. After using the medicine, you must be near the toilet.

### **Important information about some excipients found in the composition of E.S. ENEMA FOR ADULTS**

#### **Use with other medicines**

If you are currently using any prescription or non-prescription medication of the following type or you have used it recently, please inform your doctor or pharmacist about them:

- High blood pressure or heart disease medications (calcium channel blockers)
- Bladder emptying drugs (diuretics)
- Some medicines for mental distress (lithium)
- Medicines that can dehydrate the body or medicines that can alter the salt level (potassium, sodium, phosphate, or water) in the body, known as electrolyte balance

*If you are currently using any prescription or non-prescription medication of the following type or you have used it recently, please inform your doctor or pharmacist about them.*

## 6. How to use E.S. ENEMA FOR ADULTS?

- **Instructions for appropriate use and dose/administration frequency:**

It is only taken rectally (anally). Do not take it by oral ingestion.

In adults and children over 12 years of age, a maximum of one bottle per day is used, unless otherwise indicated by the physician.

Before starting to inject, remove the white protective cap.

Unless otherwise recommended by your doctor, E.S. ENEMA FOR ADULTS should not be used for longer than 14 days.

If there is resistance, use is discontinued. Strain of E.S. ENEMA FOR ADULTS can cause damage.

**Note:** There is no need to completely empty the bottle. For effective use, the amount in the bottle is more than the therapeutic dose. After use, some liquid will increase in the bottle. The position is maintained until it is completely emptied. (Usually 2 - 5 minutes)

- **Route and Method of administration:**

Left side position:

Lie on the left. Knees bend to the right and arms swing freely.



Knee-chest position:

Kneel down. The head is tilted down and the chest is moved forward. The left side of the face is brought closer to the surface and placed comfortably on the left arm.



8. Choose the appropriate one of the above two positions (left lateral position or knee-chest position).
9. Remove the white protective cover. Holding the bottle upright, grasp the cap of the corrugated bottle with your finger. With the other hand, gently pull off the protective cover.
10. Gently insert the tip of the vial into the rectum with steady pressure, aiming at the anus center.
11. **Do not use excessive force while the tip is inserted into the rectum as it may cause damage.**
12. If the bowel emptying movement is given to the anus (providing a stool movement), the tip is placed more easily. This movement allows the muscles around the anus to relax.
13. Squeeze the bottle until almost all of the liquid is drained.
14. Remove the tip from the rectum and hold your position until the bowel emptying movement begins (normally 2-5 minutes).

**Various age groups:**

Pediatric Use: For children aged 3-12, "E.S. ENEMA FOR CHILDREN" form is available. (E.S. ENEMA FOR ADULTS dose for adults is 135 mL, for children, the dose is 67.5 ml, which is equivalent to half of this dose.)

## **Special use cases:**

### **Renal/Hepatic Impairment:**

If you have liver dysfunction, if you are on a salt-banned diet or if you have kidney disease, do not use unless your doctor recommends it.

In elderly and sluggish patients and uncontrolled arterial hypertension, abdominal water accumulation, heart disease, intestinal lining (rectal mucosa) changes (e.g. ulcer, fissure) with colostomy or persistent low calcium level (hypocalcemia), blood potassium level It should be used with caution in people with electrolyte disorders such as low blood pressure (hypokalemia), high phosphate level in the blood (hyperphosphatemia), increased sodium level in the blood (hypernatremia), and especially in diabetes mellitus (acidosis).

*Talk to your doctor or pharmacist if you have the impression that the effect of E.S. ENEMA FOR ADULTS is too strong or weak.*

### **If you have used more E.S. ENEMA than you should**

If more than necessary amount of E.S. ENEMA FOR ADULTS is taken, seek professional help or contact a health center.

Overdose or retention; Increased sodium level in the blood (hypernatremia), increased blood phosphate level (hyperphosphatemia), decreased calcium level (hypocalcemia) and decreased potassium level in the blood (hypokalemia), such as salt and mineral levels (electrolytes), may cause impairment in the body. In addition to these, dehydration (dehydration) and hypovolemia (decrease in blood volume) may occur with some signs and symptoms (eg metabolic acidosis, renal failure and tetany). Some severe electrolyte disturbances can lead to heart rhythm disturbances (cardiac arrhythmia) and death. If you have overdosed, you should be followed carefully. **Electrolyte disturbance treatment requires urgent medical attention with appropriate electrolyte and fluid replacement.**

*Talk to a doctor or pharmacist if you have used more than you should use from E.S. ENEMA FOR ADULTS.*

### **If you forget to use E.S. ENEMA FOR ADULTS**

If you forget to use E.S. ENEMA, use it again in normal doses.

*Do not take a double dose to make up for forgotten doses.*

### **Effects which may occur when treatment with E.S. ENEMA FOR ADULTS is concluded**

There is no data on any effect when treatment is terminated.

## **6. What are the possible side effects?**

As with all medicines, there may be side effects in people who are sensitive to the ingredients of E.S. ENEMA FOR ADULTS.

The incidence of undesirable effects seen with E.S. ENEMA FOR ADULTS is unknown (cannot be estimated from the available data).

**Stop using E.S. ENEMA FOR ADULTS if any of the following occur, and immediately notify your physician or consult the emergency department of your nearest hospital:**

- Rectal bleeding (bloody stool or blood coming from the bowel)
- Severe sudden allergic reaction (rash, itching, swelling of the face and lips, or swelling of the mouth and throat to make swallowing or breathing difficult) with difficulty breathing and feeling faint or dizzy
- No bowel movement or stool excretion after E.S. ENEMA FOR ADULTS is given.

These are all very serious side effects.

If you have one of these, you may need urgent medical attention or hospitalization.

**If you notice any of the following, immediately report to your doctor or contact the emergency department of your nearest hospital:**

- Dehydration (excessive dehydration of the body)
- Allergic reactions (itching, hives (urticaria))
- Muscle twitching or sudden contractions due to changes in the amount of electrolytes (salts) in the blood.
- Abdominal pain or bloating due to gas accumulation in the intestines
- Vomiting or nausea
- Itching or burning in the anal area
- Formation of liquid-filled blisters on the skin
- Diarrhea
- Tremor accompanied by a feeling of cold
- Pricking
- Increased levels of phosphate in the blood (hyperphosphatemia)
- Low calcium levels (hypocalcemia)
- Low levels of potassium in the blood (hypokalaemia)
- Increased sodium level in the blood (hypernatremia)
- Disruption of acid excretion in the body (metabolic acidosis)

*If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.*

### **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.

## **7. How to store E.S. ENEMA FOR ADULTS**

*Keep E.S. ENEMA FOR ADULTS out of the reach and sight of children and within its packaging*

Do not buy cut or opened packages.

Store at room temperature below 25°C.



Do not freeze.

**Use in compliance with the expiry date.**

*Do not use E.S. ENEMA FOR ADULTS after the expiry date which is stated on the packaging.*

***Marketing Authorization Holder:***

HAVER FARMA İlaç A.Ş.  
Akbaba Mah. Maraş Cad. No:52/2/1 34820  
Beykoz / İSTANBUL  
Tel: 0216 324 38 38  
Fax: 0216 317 04 98

***Manufacturing Site:***

Farmamag Ambalaj San. ve Tic. A.Ş.  
Bağlariçi Caddesi No.:14 Kat:2 Avcılar - İSTANBUL

This patient information leaflet approved in 02/02/2015

THE FOLLOWING INFORMATION IS FOR THE HEALTH PERSONNEL WHO APPLY THIS MEDICINE:

Congenital megacolon should not be used in people with intestinal obstruction, imperforate anus, or congestive heart disease. It should be used with caution in people who have had renal impairment, pre-existing electrolyte disturbances, or who have undergone colostomy or use diuretics or who are taking medications such as hypocalcemia, hyperphosphatemia, hypernatremia, or acidosis.

Since E.S. ENEMA has adult and child forms, prescription should be done accordingly.

## PATIENT INFORMATION LEAFLET

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

**Administered via rectal for children.**

- ***Active Ingredients:***

An administration dose of 59 mL contains;

Sodium dihydrogen phosphate 9.5 g

Disodium hydrogen phosphate 3.5 g

- ***Excipients:***

Methylparaben sodium, deionized water

Nozzle lubricant: White soft paraffin

**Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.**

- *Keep this patient information leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

### **What is in this leaflet:**

**6. What E.S. ENEMA FOR CHILDREN is and what it is used for?**

**7. What you need to know before you use E.S. ENEMA FOR CHILDREN**

**8. How to use E.S. ENEMA FOR CHILDREN?**

**9. What are the possible side effects?**

**10. How to store E.S. ENEMA FOR CHILDREN.**

### **4. What E.S. ENEMA FOR CHILDREN is and what it is used for?**

- E.S. ENEMA FOR CHILDREN is used to relieve temporary constipation or to cleanse the bowel.
- E.S. ENEMA FOR CHILDREN is a bowel cleanser that increases the amount of water in the stool and thus helps to excrete and cleanse the bowel.
- E.S. ENEMA FOR CHILDREN contains saline laxative. Saline laxatives provide water retention in the bowel (sigmoid colon). As a result of this effect, the bowel is stimulated within 2 to 5 minutes and excretion takes place.
- In endoscopy, bowel surgery and X-ray examinations where temporary constipation or intestinal cleansing is required,

- It is used to clean / evacuate the bowel before rectal examination or control procedures.
- Soft and flexible nozzle provides a comfortable administration in a short time as it contains lubricant.
- Latex is not used in any E.S. ENEMA product.
- It is used in children between 3 and 5 years old.
- It is used in children between 5 and 12 years old.

## **5. What you need to know before you use E.S. ENEMA FOR CHILDREN**

With the administration, the excretion of stool will be watery, so plenty of fluids should be taken to prevent fluid loss in the body.

It may be harmful to take more than one bottle of E.S. ENEMA within 24 hours. Do not use laxative products for longer than two weeks, unless recommended by your doctor.

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

In case of oral ingestion, seek medical help immediately or contact a poison control center.

Rectal discomfort or a burning sensation may occur.

### **DO NOT use E.S. ENEMA FOR CHILDREN in the following situations.**

- If you are allergic to any of the active substance or excipients in E.S. ENEMA FOR CHILDREN
- If you have excessive enlargement of your large bowel (megacolon)
- If there is a narrowing or defect in the anus or rectum
- If there is an obstruction in the large intestine (Hirschsprung disease)
- If there is a suspected digestive system obstruction
- If there is a blockage in the digestive system or defects in normal bowel movements

If it has been indicated by your doctor that you have or may have even one of the following conditions:

- Appendicitis
- Wimble / damaged or clogged digestive system
- Inflammatory bowel disease
- Rectal bleeding
- If there is a problem with the heart pumping blood to the whole body (congestive heart failure)
- Nausea or thirst
- Abdominal pain
- Under 3 years old

### **USE E.S. ENEMA FOR CHILDREN CAREFULLY in the following situations.**

- Have uncontrolled blood pressure
- If you have heart or kidney disease
- If you have water accumulation in the stomach
- If you have rectal ulcers or cracks
- If you have had colostomy surgery
- Changes in salt levels in your body (electrolyte disturbances)

If these warnings are valid for you, even at any time in the past, please consult your doctor.

### **Using USE E.S. ENEMA FOR CHILDREN with food and drink:**

There is no interaction with food and drinks in terms of administration method.

## **Pregnancy**

*Consult your doctor or your pharmacist before using the drug.*

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

*If you notice you are pregnant during treatment, consult your doctor or pharmacist immediately.*

## **Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

Since sodium phosphate can pass into breast milk, the milk formed within 24 hours after E.S. ENEMA intake should be expelled. Breastfeeding is recommended 24 hours after this procedure.

## **Driving and using machines**

E.S. ENEMA has no direct effect on the driving and using machines. Dizziness may occur due to dehydration. After using the medicine, you must be near the toilet.

## **Important information about some excipients found in the composition of E.S. ENEMA FOR CHILDREN**

### **Use with other medicines:**

If you are currently using any prescription or non-prescription medication of the following type or you have used it recently, please inform your doctor or pharmacist about them:

- High blood pressure or heart disease medications (calcium channel blockers)
- Bladder emptying drugs (diuretics)
- Some medicines for mental distress (lithium)
- Medicines that can dehydrate the body or medicines that can alter the salt level (potassium, sodium, phosphate, or water) in the body, known as electrolyte balance

*If you are currently using any prescription or non-prescription medication of the following type or you have used it recently, please inform your doctor or pharmacist about them.*

## **6. How to use E.S. ENEMA FOR CHILDREN?**

### **• Instructions for appropriate use and dose/administration frequency:**

It is only taken rectally (anally).

Unless otherwise specified by the physician;

No more than one bottle per day for children between the ages of 5 and 12,

A maximum of half a bottle per day is used in children aged 3 to 5 years.

Before starting to inject, remove the white protective cap.

Unless otherwise recommended by your doctor, E.S. ENEMA FOR CHILDREN should not be used for longer than 14 days.

If there is resistance, use is discontinued. Force of Enema can cause damage.

**Note:** There is no need to completely empty the bottle. For effective use, the amount in the bottle is more than the therapeutic dose. After use, some liquid will increase in the bottle. The position is maintained until it is completely emptied. (Usually 2 - 5 minutes)

- **Route and Method of administration:**

Left side position:

Lie on the left. Knees bend to the right and arms swing freely.



Knee-chest position:

Kneel down. The head is tilted down and the chest is moved forward. The left side of the face is brought closer to the surface and placed comfortably on the left arm.



8. Choose the appropriate one of the above two positions (left lateral position or knee-chest position).
  9. Remove the white protective cover. Holding the bottle upright, grasp the cap of the corrugated bottle with your finger. With the other hand, gently pull off the protective cover.
  10. Gently insert the tip of the vial into the rectum with steady pressure, aiming at the anus center.
  11. **Do not use excessive force while the tip is inserted into the rectum as it may cause damage.**
  12. If the bowel emptying movement is given to the anus (providing a stool movement), the tip is placed more easily. This movement allows the muscles around the anus to relax.
  13. Squeeze the bottle until almost all of the liquid is drained.
  14. Remove the tip from the rectum and hold your position until the bowel emptying movement begins (normally 2-5 minutes).
- **Special use cases:**

**Renal/Hepatic Impairment:**

If you have liver dysfunction, if you are on a salt-banned diet or if you have kidney disease, do not use unless your doctor recommends it.

In addition, uncontrolled arterial hypertension, accumulation of water in the abdomen, heart disease, changes in the intestinal lining (rectal mucosa) (e.g. ulcer, fissure) with colostomy or chronic low calcium level (hypocalcemia), low potassium level in the blood (hypokalemia) It should be used with caution in people with electrolyte disorders such as high phosphate level in the blood (hyperphosphatemia), increased sodium level in the blood (hyponatremia), and especially in diabetes mellitus with acidosis.

*Talk to your doctor or pharmacist if you have the impression that the effect of E.S. ENEMA FOR CHILDREN is too strong or weak.*

**If you have used more E.S. ENEMA FOR CHILDREN than you should**

If more than necessary amount of E.S. ENEMA FOR CHILDREN is taken, seek professional help or contact a health center.

Overdose or retention; Increased sodium level in the blood (hypernatremia), increased blood phosphate level (hyperphosphatemia), decreased calcium level (hypocalcemia) and decreased potassium level in the blood (hypokalemia), such as salt and mineral levels (electrolytes), may cause impairment in the body. In addition to these, dehydration (dehydration) and hypovolemia (decrease in blood volume) may occur with some signs and symptoms (eg metabolic acidosis, renal failure and tetany). Some severe electrolyte disturbances can lead to heart rhythm disturbances (cardiac arrhythmia) and death. If overdose is taken, careful monitoring is required. **Electrolyte disturbance treatment requires urgent medical attention with appropriate electrolyte and fluid replacement.**

*Talk to a doctor or pharmacist if you have used more than you should use from E.S. ENEMA FOR ADULTS.*

**If you forget to use E.S. ENEMA FOR CHILDREN**

If you forget to use E.S. ENEMA CHILDREN, use it again in normal doses.

*Do not take a double dose to make up for forgotten doses.*

**Effects which may occur when treatment with E.S. ENEMA FOR CHILDREN is concluded**

There is no data on any effect when treatment is terminated.

**6. What are the possible side effects?**

As with all medicines, there may be side effects in people who are sensitive to the ingredients of E.S. ENEMA FOR CHILDREN.

The incidence of undesirable effects seen with E.S. ENEMA FOR CHILDREN is unknown (cannot be estimated from the available data).

**Stop using E.S. ENEMA FOR CHILDREN if any of the following occur, and immediately notify your physician or consult the emergency department of your nearest hospital:**

- Rectal bleeding (bloody stool or blood coming from the bowel)
- Severe sudden allergic reaction (rash, itching, swelling of the face and lips, or swelling of the mouth and throat to make swallowing or breathing difficult) with difficulty breathing and feeling faint or dizzy.
- No bowel movement or stool excretion after E.S. ENEMA FOR CHILDREN is given.

These are all very serious side effects.

If you have one of these, you may need urgent medical attention or hospitalization.

**If you notice any of the following, immediately report to your doctor or contact the emergency department of your nearest hospital:**

E.S. ENEMA should be used as specified in the application route and method. If resistance is encountered, use should be discontinued.

In case of oral ingestion, seek medical help immediately or contact a poison control center. After administration,

- Rectal bleeding
- If there is no movement in the bowel or fecal excretion after E.S. ENEMA is given, immediately inform your doctor or go to the nearest emergency department.

All these are serious side effects. Emergency medical attention may be required.

**If you notice any of the following, tell your doctor:**

- Itching
- Hives (urticaria)
- More fluid loss than normal (dehydration)
- Increased levels of phosphate in the blood (hyperphosphatemia)
- Low calcium levels (hypocalcemia)
- Low levels of potassium in the blood (hypokalaemia)
- Increased sodium level in the blood (hypernatremia)
- Disruption of acid excretion in the body (metabolic acidosis)
- Nausea
- Vomiting
- Abdominal pain
- Abdominal bloating (abdominal distension)
- Diarrhea
- Ache
- Anal itching
- Chill
- Rectal irritation
- Swelling
- Pricking

These are mild side effects of ENEMA FOR CHILDREN.

*If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.*

**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.

**7. How to store E.S. ENEMA FOR CHILDREN.**

*Keep E.S. ENEMA FOR CHILDREN out of the reach and sight of children and within its packaging.*

Do not buy cut or opened packages.

Store at room temperature below 25°C.

Do not freeze.



**Use in compliance with the expiry date.**

*Do not use E.S. ENEMA FOR CHILDREN after the expiry date which is stated on the packaging.*

***Marketing Authorization Holder:***

Haver Farma İlaç A.Ş.  
Akbaba Mah. Maraş Cad. No:52/2/1 34820  
Beykoz / İSTANBUL  
Tel: 0216 324 38 38  
Fax: 0216 317 04 98

***Manufacturing Site:***

Farmamag Ambalaj San. ve Tic. A.Ş.  
Bağlariçi Caddesi No.:14 Kat:2 Avcılar - İSTANBUL

This patient information leaflet approved in 02/02/2015

THE FOLLOWING INFORMATION IS FOR THE HEALTH PERSONNEL WHO APPLY THIS MEDICINE:

Congenital megacolon should not be used in people with intestinal obstruction, imperforate anus, or congestive heart disease. It should be used with caution in people who have had renal impairment, pre-existing electrolyte disturbances, or who have undergone colostomy or use diuretics or who are taking medications such as hypocalcemia, hyperphosphatemia, hypernatremia, or acidosis. Since E.S. ENEMA has adult and child forms, prescription should be done accordingly.