

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Cleenema Ready-to-Use 21.4g/9.4g Enema

Sodium Dihydrogen Phosphate Dihydrate / Disodium Phosphate Dodecahydrate

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or doctor if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### What is in this leaflet

1. What Cleenema Ready-to-Use Enema is and what it is used for.
2. What you need to know before you use Cleenema Ready-to-Use Enema.
3. How to use Cleenema Ready-to-Use Enema.
4. Possible side effects.
5. How to store Cleenema Ready-to-Use Enema.
6. Contents of the pack and other information.

#### 1. What Cleenema Ready-to-Use Enema is and what it is used for

Cleenema Ready-to-Use Enema is a bowel cleanser that acts by increasing the water content of your stools and in this way helps to relieve constipation and clear the bowel.

It can be used in the relief of occasional constipation and where bowel cleansing is required, such as prior to your endoscopy, bowel surgery or X-ray examination.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### 2. What you need to know before you use Cleenema Ready-to-Use Enema

**Do not use Cleenema Ready-to-Use Enema and tell your doctor if you:**

- Are **allergic** (hypersensitive) to sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate or any of the other ingredients of this medicine (listed in section 6).
- Have a **swollen large bowel** (also known as megacolon).
- Have a **narrowing or incomplete opening** of the anus or rectum.
- Have a **blockage** of the lower colon (Hirschsprung's disease).
- Have a suspected **blockage of the gut**.
- Have **blockage of the gut or failure of normal bowel movements** (sometimes called paralytic ileus).
- Have been told by your doctor that you may have:
  - **appendicitis**
  - **a pierced/damaged or blocked gut**
  - **an active inflammatory bowel disease** (such as Crohn's disease or ulcerative colitis).
- Have undiagnosed **bleeding of the back passage**.
- Have **kidney problems**.
- Have **congestive heart failure** (your heart is unable to properly pump blood around the body).
- Have **recently been sick or feel sick or thirsty**.
- Have a pain in your **stomach** (abdominal pain).
- The patient is under 3 years of age.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Cleenema Ready-to-Use Enema if:

- You are frail or elderly.
- You have uncontrolled blood pressure.
- You have a heart or kidney condition.
- You suffer from ascites (excess fluid in the peritoneal cavity).
- You suffer from rectal ulceration (ulceration of the back passage) or fissures (tears in the skin of the back passage).
- You have had a colostomy.
- You suffer from electrolyte disturbances (changes in the salt levels in the body such as low calcium, low potassium, high phosphate or high sodium levels).

Please consult your doctor, even if these statements were applicable to you at any time in the past. You may need to be more closely supervised during treatment.

### **Other medicines and Cleenema Ready-to-Use Enema**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- medicines for the treatment of high blood pressure (hypertension) or angina (calcium channel blockers).
- medicines to empty the bladder (diuretics).
- certain medicines for mental disorders (lithium).
- any other medicines that could make you dehydrated or alter the salt levels (potassium, sodium, phosphate or water) in your body, known as your electrolyte balance.
- certain medicines for cleaning the bowel (sodium phosphates).
- medicines that alter the rhythm of your heart (prolong the QT interval such as amiodarone, arsenic trioxide, astemizole, azothromycin, erythromycin, claritromycin, chlorpromazine, cisapride, citalopram, domperidone, terfenadine, procainamide).
- non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin or ibuprofen.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

As the main ingredients contained in Cleenema Ready-to-Use Enema may pass into breast milk, it is advised that breast milk is expressed and discarded for at least 24 hours after receiving the Cleenema Ready-to-Use Enema.

### **Driving and using machines**

Whilst there are no direct effects of Cleenema Ready-to-Use Enema on your ability to drive or use machinery, you should remain near toilet facilities after using this medicine.

**Cleenema Ready-to-Use Enema contains benzalkonium chloride** which is an irritant and may cause skin reactions.

### **3. How to use Cleenema Ready-to-Use Enema**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### **Adults and children 12 years old and over:**

The recommended dose is one bottle (118ml delivered dose) no more than once daily or as directed by your doctor.

**Children over 3 years to under 12 years old:**  
as directed by your doctor.

**Do not administer to children under 3 years of age.**

For rectal use only.

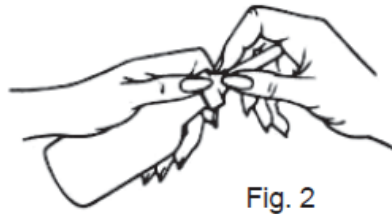
Unless directed by your doctor, Cleenema Ready-to-Use Enema should not be used for more than one week. Administration of more than one enema in a 24 hour period can be harmful.

**Administration:**

1. Lie on your left side with both knees bent and your arms at rest in front of you (Fig. 1, below).



2. **Remove the orange protective shield.** Pull the shield gently while holding the bottle upright and grasping the grooved bottle cap with your fingers (Fig. 2, below).



3. With a steady pressure, gently insert the enema Comfortip into the rectum with the tip pointing towards your navel.

4. Squeeze the bottle until nearly all the liquid has been emptied.

**Discontinue use if any resistance is encountered. Forcing an enema can result in injury.**

NOTE: It is not necessary to empty the unit completely. The bottle contains more than the amount of liquid needed for effective use, so a small residue will remain.

5. Gently remove the nozzle from your rectum. It is normal to experience some leakage of the enema liquid.

6. Remain in the same position (Fig. 1, above) until the urge to evacuate your bowels is strong - usually within 2 to 5 minutes.

7. Return the used enema to the carton for disposal.

**If rectal bleeding is noticed,** administration must be discontinued immediately and you must **contact a doctor immediately.**

**Be prepared to expect frequent loose bowel movements within 5 minutes** of taking a dose of Cleenema Ready-to-Use Enema. This is normal and shows that the medicine is working. **If you have not had a bowel movement within this time, consult your doctor.** Do not use any more Cleenema Ready-to-Use Enema unless instructed to do so by your doctor. Remain near a toilet until the effects have worn off.

**Drink plenty of clear fluids e.g. water, clear soups, herbal tea, black tea or black coffee or diluted cordials/fruit juice without pulp (but not red or purple coloured juices) to avoid dehydration.** In general you should drink 250ml (a small tumbler-sized glass) every hour until the effect of the Cleenema Ready-to-Use Enema has worn off. After this, drink clear fluids, preferably water, to satisfy your thirst until after your hospital procedure, or as directed by your doctor.

**If you use more Cleenema Ready-to-Use Enema than you should, or if you accidentally ingest (drink) the medicine,** talk to a doctor or pharmacist immediately. If you use more Cleenema Ready-to-Use Enema than you should, you may feel dehydrated, be thirsty or have muscular rigidity. If possible take your bottle or the carton with you to show the doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Cleenema Ready-to-Use Enema may very rarely (one out of 10,000 people) cause:

- Hypersensitivity: allergic reactions (with or without rash).
- Dehydration.
- Muscle twitches and spasms due to changes in the amounts of salts (electrolytes) in the blood.
- Abdominal pain or bloating (distension).
- Gastrointestinal pain.
- Nausea or vomiting.
- Anal itching, stinging, pain or discomfort.
- Blisters.
- Diarrhoea.
- Chills.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Cleenema Ready-to-Use Enema**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the packaging. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not refrigerate.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. Contents of the pack and other information**

##### **What Cleenema Ready-to-Use Enema contains**

Active substances: Each 118ml dose delivers the equivalent of 21.4g (18.1% w/v) Sodium Dihydrogen Phosphate Dihydrate and 9.4g (8.0% w/v) Disodium phosphate Dodecahydrate.

Contains 4.4g sodium per delivered dose.

The other ingredients (excipients) are Benzalkonium Chloride, Disodium Edetate, Purified Water.

The nozzle lubricant is white soft paraffin.

Contains 70mg benzalkonium chloride per delivered dose.

### **What Cleenema Ready-to-Use Enema looks like and the contents of the pack**

Cleenema Ready-to-Use Enema is a clear, colourless, odourless solution contained in a white plastic bottle with a white cap and orange protective shield. The bottle contains 133ml of Cleenema Ready-to-Use Enema, of which 118ml is the delivered dose.

### **Marketing Authorisation Holder and Manufacturer**

Casen Recordati, S.L.  
Autovía de Logroño, km 13,300,  
50180 Utebo, Zaragoza, Spain.

Marketing Authorisation Number:  
PA 2028/1/1

If you have any questions or comments about this product, please contact us on:  
Ireland: 1800 303 351 / [medinfo@recordati.co.uk](mailto:medinfo@recordati.co.uk)

This leaflet was revised in June 2022.