Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Contains 4.4 g Sodium per 118ml delivered dose.

Excipients: contains 70mg benzalkonium chloride per 118ml delivered dose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Rectal Solution (Enema)
Clear, colourless, odourless solution, free from precipitate and turbidity.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- For use in the relief of occasional constipation.
- For use where bowel cleansing is required, such as before and after lower bowel surgery, delivery and post partum, before proctoscopy, sigmoidoscopy and before radiological examinations of the lower bowel.

4.2 Posology and method of administration

Posology
Adults and Children over 12 years old: 1 bottle (118ml delivered dose) no more than once daily or as directed by a physician (see section 4.4).

Elderly patients: 1 bottle (118ml delivered dose) no more than once daily or as directed by a physician. Cleenema Ready to Use enema should be used with caution in the elderly (see section 4.4).

Children aged 3 years to less than 12 years: As directed by a physician (see section 4.4 and 4.9).

Cleenema Ready-to-Use Enema is contraindicated in children under 3 years of age (see section 4.3).

Renal impairment.
Do not administer to patients with clinically significant impairment of renal function (see section 4.3).

The product should be used with caution in patients with impaired renal function, when the clinical benefit is expected to outweigh the risk of hyperphosphataemia (see section 4.4).

Hepatic Impairment
No dose adjustment is required in patients with hepatic impairment.

Administration of more than one enema in a 24 hour period can be harmful. Unless directed by a physician, Cleenema Ready-to-Use Enema should not be used for more than one week (see section 4.4).

Method of administration

For rectal use only:

Lie on left side with both knees bent, arms at rest.

Remove orange protective shield.

With steady pressure, gently insert enema Comfortip into anus with nozzle pointing towards navel.

Squeeze bottle until nearly all liquid is expelled.

Discontinue use if resistance is encountered. Forcing the enema can result in injury.

Return enema to carton for disposal.
Generally, 2 to 5 minutes are sufficient to obtain the desired effect. If delayed discontinue further use and consult a physician.

For occasional constipation rectal enemas are to be used to provide short-term relief only.

4.3 Contraindications

Cleenema Ready-to-Use Enema is contraindicated in patients with:

- Hypersensitivity to active ingredients or to any of the excipients listed in section 6.1 .
- Conditions causing decreased gastric motility, e.g.,

o suspected intestinal obstruction
o paralytic ileus
o anorectal stenosis
o imperforate anus
o congenital or acquired megacolon
o Hirschsprung's disease

- Undiagnosed gastrointestinal pathology, e.g.,

o symptoms of appendicitis, intestinal perforation or active inflammatory bowel disease
o undiagnosed rectal bleeding

- Congestive heart failure.
- Dehydration and generally in all cases where absorption capacity is increased or elimination capacity is decreased.
- Children under 3 years of age.
- Clinically significant impairment of renal function.

No other sodium phosphates preparations including sodium phosphates oral solution or tablets should be given concomitantly (see section 4.5).

4.4 Special warnings and precautions for use

Do not use Cleenema Ready-to-Use Enema when nausea, vomiting or abdominal pain is present unless directed by a physician.

Patients should be advised to expect liquid stools and should be encouraged to drink clear liquids to help prevent dehydration, especially patients with conditions that may predispose to dehydration or those taking medications which may decrease glomerular filtration rate, such as diuretics, angiotensin converting enzyme inhibitors (ACE-Is), angiotensin receptor blockers (ARBs) or non-steroidal anti-inflammatory drugs (NSAIDs).

Since CleenemaReady-to-Use 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 and hypokalemia may occur with clinical signs like tetany and renal failure. Electrolyte shifts are of particular concern in children with megacolon or any other condition where there is retention of enema solution, and in patients with co-morbidities. That is why Cleenema Ready-to-Use Enema should be used with caution in: elderly or debilitated patients and in patients with uncontrolled arterial hypertension, ascites, heart disease, rectal mucosal changes (ulcers, fissures), colostomy patients who are taking diuretics or other medications which may affect electrolyte levels, who are taking medications known

to prolong the QT interval (such as amiodarone, arsenic trioxide, astemizole, azothromycin, erythromycin, chlaritromycin, chlorpromazine, cisapride, citalopram, domperidone, terfenadine, procainamide), or pre-existing electrolyte imbalance such as hypocalcaemia, hypokalaemia, hyperphosphataemia, hypernatraemia . Use also with caution in patients who are taking medications known to affect renal perfusion or function, or hydration status. Where electrolyte disorders are suspected and in patients who may experience hyperphosphataemia, electrolyte levels should be monitored before and after administration of Cleenema Ready-to-Use Enema.

The product should be used with caution in patients with impaired renal function, when the clinical benefit is expected to outweigh the risk of hyperphosphataemia.

Repeated and prolonged use of CleenemaReady-to-Use Enema is not recommended as it may cause habituation. Administration of more than one enema in a 24 hour period can be harmful.Unless directed by a physician, Cleenema Ready-to-Use Enema should not be used for more than one week.

CleenemaReady-to-Use Enema should be administered according to the instructions for use and handling (see section 4.2). Patients should be warned to stop administration if resistance is encountered as forced administration of the enema may cause injury. Rectal bleeding after using Cleenema Ready-to-Use Enema may indicate a serious condition. If this occurs, administration must be discontinued immediately and the condition of the patient assessed by a physician.

In general, evacuation occurs approximately 5 minutes after CleenemaReady-to-Use Enema administration; therefore, retention times over 5 minutes are not recommended. If evacuation does not occur after using Cleenema Ready-to-Use Enema or if the retention time lasts for more than 10 minutes, serious side effects could occur. No further administrations should be given and the condition of the patient should be assessed by a physician who will decideiflaboratory tests should be completed in order to detect possible electrolyte abnormalities and to minimize the risk of severe hyperphosphatemia (see sections 4.8 and 4.9).

This medicine contains benzalkonium chloride which is an irritant and may cause skin reactions.
Keep all medicines out of the sight and reach of children.

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 phosphates preparations including sodium phosphates oral solution or tablets should be given concomitantly (see section 4.3)
As hypernatraemia is associated with lower lithium levels, concomitant use of CleenemaReady-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

As there is no relevant data available to evaluate the potential for foetal malformation or other foetotoxic effects when administered during pregnancy Cleenema Ready-to-Use Enema should only be used as directed by a physician at the time of delivery or postpartum.

As sodium phosphate may pass into the 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.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Cleenema Ready-to-Use is well tolerated when used as indicated. However, adverse events possibly associated with the use of Cleenema Ready-to-Use Enema have been infrequently reported. In some cases, adverse events may occur, especially if the enema is misused.

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Organized by MedDRA System Organ Class the undesirable effects are listed below using the following frequency classification: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data):

Immune System Disorders:
Very rare: Hypersensitivity e.g. urticaria.

Skin and subcutaneous tissue disorders
Very rare: blister, pruritus, stinging.

Metabolism and nutrition disorders
Very rare: dehydration, hyperphosphataemia, hypocalcaemia, hypokalaemia, hypernatremia, metabolic acidosis.

Gastrointestinal disorders:
Very rare: nausea, vomiting, abdominal pain, abdominal distension, diarrhoea, gastrointestinal pain, anal discomfort and proctalgia.

General disorders and administration site conditions:
Very rare: rectal irritation, pain, stinging, chills.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance,
Website: www.hpra.ie.

4.9 Overdose

There have been fatalities when Cleenema Ready-to-use Enema has been administered in excessive doses or retained, used in children or used in obstructed patients.

Hyperphosphataemia, hypocalcaemia, hypernatraemia, hypernatraemia dehydration, hypokalemia, hypovolemia, acidosis and tetany may occur in overdose or retention.

Recovery from the toxic effects can normally be achieved by rehydration. In severe cases correction of electrolyte changes by providing calcium and magnesium salts (10% calcium gluconate) while promoting elimination of exogenous phosphorus and the use of dialysis should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sodium phosphate enema, ATC code: A06AG01.

Cleenema Ready-to-Use Enema will act as a saline laxative when administered by the rectal route. Fluid accumulation in the lower bowel produces distension and promotes peristalsis and bowel movement with only the rectum, sigmoid and part or all of the descending colon being evacuated.

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 has 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

Disodium Edetate
Benzalkonium Chloride
Purified Water
Nozzle lubricant: White Soft Paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate.

6.5 Nature and contents of container

Cleenema Ready-to-Use Enema is supplied in a 133ml disposable LDPE squeeze bottle, fitted with a LDPE cap, neoprene/isoprene latex-free valve and a soft pre-lubricated Comfortip (ethylene vinyl acetate), which is covered by a protective LDPE shield until use.

The bottle contains 133ml of Cleenema Ready-to-Use Enema, which gives a delivered dose of 118ml.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Casen-Recordati S.L.
Autovia De Logrono, km. 13,300
50180 Utebo (Zaragoza)
Spain

8 MARKETING AUTHORISATION NUMBER

PA2028/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 February 1995

Date of last renewal: 16 February 2010

10 DATE OF REVISION OF THE TEXT

August 2022