Prescribing Information (Summary of Product Characteristics)

1. Name of the medicinal product
Freeflo Enema

2. Qualitative and quantitative composition
Each 118 ml contains:
Disodium hydrogen phosphate dodecahydrate BP 9.4 g
Sodium dihydrogen phosphate dihydrate BP 21.4 g

For full list of excipients, see section 6.1.

3. Pharmaceutical form
Rectal Solution (Enema).

Description: Clear, colorless solution.

Category: Prescription Only Medicine (POM)

4. Clinical particulars

4.1.Therapeutic indications
- Occasional constipation.
- Cases requiring cleansing of the large intestine, for example before and after surgery on the colon, during and after childbirth, before proctoscopy, sigmoidoscopy or colonoscopy, and also before the radiological examination of the large intestine.

4.2.Posology and method of administration
Posology
Adults, Elderly 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).

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

Freeflo 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

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 into anus with nozzle pointing towardsnavel.
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
Freeflo enema is contraindicated in patients with:
- Hypersensitivity to active ingredients or to any of the excipients.
- Conditions causing increased absorption capacity or decreased elimination capacity, such as when bowel obstruction or decreased bowel motility is present; e.g.,

- Suspected intestinal obstruction
- Paralytic ileus
- Anorectal stenosis
- Imperforate anus
- Congenital or acquired megacolon
- Hirschsprung's disease
- Undiagnosed gastrointestinal pathology, e.g.,
- Symptoms suggestive of appendicitis, intestinal perforation or active inflammatory bowel disease
- Undiagnosed rectal bleeding
- Congestive heart failure.
- Dehydration
- 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 medicinal product in the presence of nausea, vomiting or abdominal pain 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, e.g. enalapril, ramipril, lisinopril,), angiotensin receptor blockers (ARBs, e.g. losartan, candesartan, eprosartan, irbesartan, olmesartan, telmisartan, valsartan) or non-steroidal anti-inflammatory drugs (NSAIDs).

Since the product contains sodium phosphates, there is a risk of increased sodium and phosphate concentrations, as well as a decrease in serum calcium and potassium concentrations, which may lead to hypernatremia, hyperphosphatemia, hypocalcemia, and hypokalemia with clinical features similar to tetany and renal insufficiency. Disturbance in the balance of the electrolytes is a particular concern for children suffering from megacolon or any other disease in which the fluid retention of the enema is observed and for patients with concomitant diseases.

For this reason, the drug should be prescribed with caution to the elderly or exhausted patients and patients with uncontrolled arterial hypertension, ascites, heart disease, changes in rectal mucosa (ulcers, cracks), colostomy, using diuretics or other medicinal products that affect the balance electrolytes, drugs that can extend the QT interval (e.g amiodarone, arsenic trioxide, astemizole, azithromycin, erythromycin, clarithromycin, chlorpromazine, cisapride, citalopram, domperidone, terfenadine, procainamide), or in patients with electrolyte imbalance, which was observed earlier as may hypocalcemia, hypokalemia, hypernatremia or hyperphosphatemia. Use also with caution in patients who are taking medications known to affect renal perfusion or function, or hydration status. In case of suspicion of a disturbance in electrolyte balance and presence of hypophosphatemia in patients, monitoring of electrolyte levels before and after administration of the drug should beperformed.

The drug should be used with caution in patients with impaired kidney function, in which the benefit from the use will outweigh the risk of hyperphosphatemia.

Repeated and prolonged use of the drug is not recommended because it may cause habituation. The administration of more than one enema within 24 hours may be harmful. Unless directed by a physician drug should not be used for more than one week.

Before using medicinal product, you should read the instructions for use and the rules for administration of the medicinal product. Do not insert the bottle tip into the rectum unless it has been previously lubricated with liquid paraffin/vaseline. Patients should be warned to stop administration if resistance is encountered as forced administration of the enema may cause injury. Rectal bleeding after using Freeflo 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 drug administration; therefore,

retention times over 5 minutes are not recommended. If evacuation does not occur after using drug 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 decide if laboratory tests should be completed in order to detect possible electrolyte abnormalities and to minimize the risk of severehyperphosphatemia.

This drug contains (118 ml) 80 mg of benzalkonium chloride for each dose, 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 phosphate preparations including sodium phosphate oral solution or tablets should be given concomitantly (see section 4.3).

As hypernatraemia is associated with lower lithium levels, concomitant use of Freeflo 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 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 medicinal product.

4.7.Effects on ability to drive and use machines
Not known.

4.8.Undesirable effects
Freeflo enema is well tolerated when used as indicated. However, adverse events possibly associated with the use of Freeflo 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 reactions (e.g, urticaria).

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

Metabolism and nutrition disorders:
Very rare: dehydration, hyperphosphatemia, hypocalcemia, hypokalemia, hypernatriemia, metabolic acidosis.

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

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

4.9.Overdose
There have been fatalities when Freeflo 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. Treatment of electrolyte imbalance may require immediate medical intervention with appropriate electrolyte and fluid replacement therapy.

5. Pharmacological properties
5.1.Pharmacodynamic properties
Pharmacotherapeutic group: Drugs for constipation. Enemas. Combinations.

ATC code: A06AG20
The medicinal product 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. 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
Benzalkonium chloride, Disodium edetate and Purified water.

6.2.Incompatibilities
Not applicable

6.3.Shelf life
3 Years

6.4.Special precautions for storage
Store below 30°C. Do not freeze.
Keep medicine out of reach of children.

6.5.Nature and contents of container
133 ml in LDPE white opaque bottle fitted with LDPE applicator along with overcap. Such 1 bottle is packed in a carton along with packaging insert.

6.6.Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder
Kusum Healthcare Pvt. Limited
SP-289(A), RIICO Industrial Area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan),
India.

8. Marketing Authorisation Number(s)
TAN 22 HM 0120

9. Date of first Authorisation/renewal of the Authorization
11/04/2022

10. Date of Revision of the Text