COLOPREP (LEMON/ORANGE FLAVOUR)

(Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution)

MODULE 1- ADMINISTRATIVE INFORMATION

1. NAME OF THE MEDICINAL PRODUCT

COLOPREP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Bowel Preparation Kit contains:

Two bottles of each with 177 mL of oral solution.

Each Bottle with 177 mL of Bowel Preparation Solution Contains :

Sodium Sulfate (as Anhydrous) USP 17.5 g

Potassium Sulfate BP 3.13 g

Magnesium Sulfate (as Anhydrous) USP 1.6 g

In a flavoured base

3. PHARMACEUTICAL FORM

Oral Solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

COLOPREP is a Bowel Cleansing preparation used before colonoscopy, colorectal surgeries or Radiological examination. Coloprep is not a treatment for constipation.

4.2 Posology and method of administration

Adults:

- Drug dose take 1 litre i.e., two 500 mL bottle of Coloprep solution before colonoscopy.
- Dosing interval - Drink completely Either “same day” or “two day” (split dose) regimen or as directed by the physician

Children’s:

Safety and effectiveness in pediatric patients has not been established. So, not recommended in children. **Method of Administration :** Oral

4.3 Contraindications:

Coloprep is contraindicated in patients with the following conditions:

- Hypersensitivity to the active substances or to any of the excipients listed in formulation

- Known or suspected gastrointestinal obstruction

• Bowel perforation
• Disorders of gastric emptying (e.g.: gastroparesis)
• Ileus
• Toxic colitis or toxic megacolon
• Profuse vomiting
• Severe dehydration
• Congestive heart failure
• Ascites
• Severe renal insufficiency (glomerular filtration rate <30 ml/min/1.73m2)
• Active inflammatory bowel disease (e.g. Crohn's disease, ulcerative colitis

4.5 Special warnings and precautions for use

Adequate hydration should be maintained during treatment. Coloprep should be used with caution in patients with fluid and electrolyte disturbance.

Hypovolaemia if any should be corrected before administration of bowel cleansing preparation.

4.5 Interactions with other medicinal products and other forms of interaction

• Use caution in patients using calcium channel blockers, diuretics, lithium treatment, ormedications that might affect electrolyte levels.

• Caution is also advised when taking medicines known to prolong the QT interval.• Diarrhoeais the expected outcome and concomitant oral medication administered within 1 to 3 hours of the start of the treatment and until the end of the cleansing process may be flushed from the gastrointestinal tract and the medication may not be absorbed properly. The therapeutic effect of regularly taken oral drugs with a narrow therapeutic index or short half-life (e.g. oral contraceptives, antiepileptic drugs, antidiabetics, antibiotics, levothyroxine, digoxin…) may be particularly affected.

4.6 Pregnancy and Lactation

Fertility

Pregnancy:

There are no data from the use of this product in pregnant women. Coloprep is not recommended during pregnancy.

Lactation:

It is not known whether this drug is excreted in human milk.

A risk to the newborns/infants cannot be excluded.

Breast-feeding should be discontinued during treatment with Coloprep until 48 hours after receiving the second dose of Coloprep.

4.7 Effects on ability to drive and use machines

Coloprep may cause fatigue or dizziness, probably as a result of dehydration, and this may have a mild to moderate effect on the ability to drive or use machinery.

4.8 Undesirable effects

The following is a list of possible adverse effect. These side effects are possible, but do not always occur. Some of the side-effects may be rare but serious.

- Vomiting
- Nausea
- Dizziness
- Bloating
- Stomach (abdominal) cramping
- Headache
- Urinate less than usual
- Seizures
- Ulcer of the bowel
- Worsening gout

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.13 Overdose

In case of overdose or misuse (e.g.: non-dilution of the preparation and/or insufficient water intake), nausea, vomiting, diarrhoea and electrolyte disturbances would be expected. Conservative measures are usually sufficient; oral rehydration therapy should be given. In the rare event of overdose triggering a severe metabolic disturbance, intravenous rehydration should be used.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Drugs for acid related disorders**;** Osmotically acting laxative.

ATC code: A02AF02

Mechanism of action

Coloprep is an osmotic laxative. Its mechanism of action primarily relies on the limited and saturable sulphate active transport process. Saturating the gastrointestinal transport mechanism leaves sulphate in the bowel. The osmotic effect of unabsorbed sulphate causes water to be retained in the bowel and leads to bowel cleansing.

Pharmacodynamic effects

The osmotic effect of the unabsorbed ions, when ingested with a large volume of water, produces a copious watery diarrhoea. In clinical trials, the mean time until a clear diarrhoea was about 6.3 hours when the doses were separated by 12 hours and about 2.8 hours when they were consumed 1 hour apart.

5.2 Pharmacokinetic properties

Sulphate absorption is a limited and saturable active transport process; absorbed sulphate is excreted primarily via the kidneys. two doses separated by 12 hours, the maximum serum concentration of sulphate was observed approximately 16 hours after the first half dose and 5 hours after the second dose [C max: 499.50 µmol/l (CV: 33.03%) in comparison to baseline values of 141 – 467 µmol/l mean 335 µmol/l (CV: 34.40%)].

Serum concentration then declined with a half-life of 8.5 hours (CV: 53.76%). Faecal excretion was the primary route of sulphate elimination (about 70% of the amount administered).

The systemic exposure (AUC and C_{max}) to sulphate after Izinova was also compared between healthy volunteers, six patients with moderate renal impairment (creatinine clearance of 30 to 49 ml/min) and six patients with mild-moderate hepatic impairment (Child-Pugh grades A (N=5) and B (N=1)), respectively. Renal impairment resulted in a decrease in the amount of sulphate excreted into urine.

Consequently, the mean AUC and C_{max} values were about 50% higher compared to healthy subjects.

Systemic exposure to sulphate was not affected by hepatic impairment. The serum sulphate concentrations returned to baseline by Day 6 after Coloprep administration in all three groups investigated. In this study Izinova use did not lead to clinically significant hypersulphataemia in patients with hepatic or renal impairment.

5.3 Preclinical safety data

Not Applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Anhydrous Citric Acid, Sodium Benzoate, Malic Acid, Sucralose, Sweet Orange flavour, Purified Water.

6.2 Incompatibilities

None Stated.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

500 mL transparent flat bottom stout PET bottle with white plastic ROPP cap with inner plug.

2 such bottles packed in a carton along with Package insert.

6.6 Special precautions for disposal and other handling No special requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES PRISMAPHARMA FZE

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