(Summary of Product Characteristics)

1. Name of the Medicinal product

COLOPREP BOWEL PREPARATION KIT (ORANGE/LEMON FLAVOUR)

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
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Visual description : Clear, colourless to pale yellow coloured liquid with characteristic odour.

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:

4.2.1 Drug dose take 1 litre i.e., two 500 mL bottle of Coloprep solution before colonoscopy.

4.2.2 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

4.4 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.

Interactions with other medicinal products and other forms of interaction

- Use caution in patients using calcium channel blockers, diuretics, lithium treatment, or medications that might affect electrolyte levels.
- Caution is also advised when taking medicines known to prolong the

QT interval.• Diarrhoea is 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

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.

4.8.1 Vomiting

4.8.2 Nausea

4.8.3 Dizziness

4.8.4 Bloating

4.8.5 Stomach (abdominal) cramping

4.8.6 Headache

4.8.7 Urinate less than usual

4.8.8 Seizures

4.8.9 Ulcer of the bowel

4.8.10 Worsening gout

Reporting 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 Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for acid related disorders**;** Osmotically acting laxative.

ATC code: A06AD10 (mineral salts in combination).

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

Not Applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container Pack Size: 500 mL

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.

Primary Packaging	500 mL transparent flat bottom stout PET bottle with white plastic ROPP cap with inner plug.
Secondary Packaging	Carton, Printed Label & Package insert.

6.6 Special Precautions for Disposal and other Handling

No special requirements.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORIZATION NUMBER

CTD 4562/R1

9. DATE OF FIRST REGISTRATION / RENEWAL OF THE REGISTRATION

2026y 14

10. DATE OF REVISION OF THE TEXT

24/08/2026