Summary of Product Characteristics

1. Name of the medicinal product
Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Bowel Preparation Solution
(COLOTOSS Bowel Preparation Kit)

2. Qualitative and quantitative composition
Each bowel preparation kit contains:
Two 177 ml bottles of oral solution.
Each bottle of bowel preparation solution contains:

Sodium Sulfate Anhydrous	USP	17.5 g
Potassium Sulfate	BP	3.13 g
Magnesium Sulfate Anhydrous	USP	1.6 g
In a flavoured base		Q.S.

Excipient(s): For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Oral Bowel Preparation Solution.
Clear Colourless liquid filled in clear PET bottle.

4. Clinical particulars
4.1 Therapeutic indications
COLOTOSS Bowel Preparation Kit is indicated for cleansing of the colon as a preparation for colonoscopy in adults.

4.2 Posology and method of administration
Dosage Regimen
The recommended dosage of COLOTOSS Bowel Preparation Kit is one bottle administered in the evening before colonoscopy
and the second bottle administered the morning of colonoscopy as follows:
Dose 1: Early in the evening prior to colonoscopy, 10 to 12 hours before the second dose.
Dose 2: The morning of colonoscopy, at least 3 ½ hours before colonoscopy.

Important Dosing Instructions
• COLOTOSS Bowel Preparation Kit must be reconstituted and diluted in water prior to ingestion. Direct ingestion of the undiluted reconstituted solution may increase the risk of nausea, vomiting, and dehydration.
• The COLOTOSS Bowel Preparation Kit is comprised of two bottles of COLOTOSS administered as a two-day regimen. Both doses of COLOTOSS Bowel Preparation Kit are required for a complete preparation for colonoscopy.
• Additional fluids must be consumed after each dose of COLOTOSS.
• Do not take other laxatives while taking COLOTOSS Bowel Preparation Kit.

Instructions for Use
Dose 1 - On the day before colonoscopy (start 10 to 12 hours prior to Dose 2):
• A light breakfast may be consumed in the morning.
• Only clear liquids may be consumed for the rest of the day after a light breakfast. Do not drink milk.
• Do not eat solid foods for the rest of the day after breakfast until the next day after colonoscopy.
• Do not eat or drink anything colored red or purple.
• Do not drink alcohol.

• Do not take oral medications within one hour of starting the first dose of COLOTOSS Bowel Preparation Kit.
Dose 2 - Next morning on the day of colonoscopy (start at least 3 1/2 hours prior to colonoscopy):
• Continue to abstain from all solid food and anything to drink other than clear liquids.
• Do not take oral medications within one hour of starting the second dose of COLOTOSS Bowel Preparation Kit.
• Complete all COLOTOSS Bowel Preparation Kit and required water at least 2 hours prior to colonoscopy or as directed by physician.
• Stop drinking clear liquids at least 2 hours before colonoscopy.

2.4 Preparation and Administration
Two doses of COLOTOSS Bowel Preparation Kit are required for a complete preparation for colonoscopy as a split-dose (two-day regimen). The total volume of liquid required is approximately 2.8 L taken orally prior to the colonoscopy, as described below.
Dose 1: Early in the evening prior to colonoscopy, 10 to 12 hours before Dose 2:
1. Open ONE (1) bottle from the COLOTOSS Bowel Preparation Kit.
2. Fill the bottle with water up to the neck of the bottle. Shake well and mix thoroughly
4. Fill the mixing container with water to the 16-ounce fill line.
5. Drink the entire amount.
6. Important: Drink two additional mixing containers filled to the 16-ounce fill line with water over the next hour (32 ounces of additional water).
Dose 2: The morning of colonoscopy, at least 3 ½ hours before colonoscopy:
1. Repeat Steps 1 through 6 from Dose 1 of the Split-Dose (2-Day Regimen).
2. Complete all COLOTOSS Bowel Preparation Kit solution and required water at least two hours prior to colonoscopy.

4.3 Contraindications
• Bowel perforation
• Gastric retention
• Ileus
•Toxic colitis or toxic megacolon
• Known allergies to components of the kit

4.4 Special warnings and precautions for use
Serious Fluid and Serum Chemistry Abnormalities
Advise all patients to hydrate adequately before, during, and after the use of COLOTOSS Bowel Preparation Kit. If a patient develops significant vomiting or signs of dehydration after taking COLOTOSS Bowel Preparation Kit, consider performing post-colonoscopy lab tests (electrolytes, creatinine, and BUN). Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment.
Patients with electrolyte abnormalities should have them corrected before treatment with COLOTOSS Bowel Preparation Kit.
In addition, use caution when prescribing COLOTOSS Bowel Preparation Kit for patients with conditions, or who are using medications, that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, arrhythmias, and renal impairment.
COLOTOSS Bowel Preparation Kit can cause temporary elevations in uric acid.

Uric acid fluctuations in patients with gout may precipitate an acute flare. The potential for uric acid elevation should be considered before administering COLOTOSS Bowel Preparation Kit to patients with gout or other disorders of uric acid metabolism.

Cardiac Arrhythmias

There have been rare reports of serious arrhythmias associated with the use of ionic osmotic laxative products for bowel preparation. Use caution when prescribing COLOTOSS Bowel Preparation Kit for patients at increased risk of arrhythmias (e.g., patients with a history of prolonged QT, uncontrolled arrhythmias, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy). Pre-dose and post-colonoscopy ECGs should be considered in patients at increased risk of serious cardiac arrhythmias.

Seizures

There have been reports of generalized tonic-clonic seizures and/or loss of consciousness associated with use of bowel preparation products in patients with no prior history of seizures. The seizure cases were associated with electrolyte abnormalities (e.g., hyponatremia, hypokalemia, hypocalcemia, and hypomagnesemia) and low serum osmolality. The neurologic abnormalities resolved with correction of fluid and electrolyte abnormalities.

Use caution when prescribing COLOTOSS Bowel Preparation Kit for patients with a history of seizures and in patients at increased risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, or patients with known or suspected hyponatremia.

Renal Impairment

Use caution when prescribing COLOTOSS Bowel Preparation Kit for patients with impaired renal function or patients taking concomitant medications that may affect renal function (such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs). Advise these patients of the importance of adequate hydration, and consider performing baseline and postcolonoscopy laboratory tests (electrolytes, creatinine, and BUN) in these patients.

Colonic Mucosal Ulcerations and Ischemic Colitis

Administration of osmotic laxative products may produce colonic mucosal aphthous ulcerations, and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of stimulant laxatives and COLOTOSS Bowel Preparation Kit may increase these risks. The potential for mucosal ulcerations resulting from the bowel preparation should be considered when interpreting colonoscopy findings in patients with known or suspect inflammatory bowel disease (IBD).

Use in Patients with Significant Gastrointestinal Disease

If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administering COLOTOSS Bowel Preparation Kit.

Use with caution in patients with severe active ulcerative colitis.

Aspiration

Use with caution in patients with impaired gag reflex and patients prone to regurgitation or aspiration.

Such patients should be observed during administration of COLOTOSS Bowel Preparation Kit.

Not for Direct Ingestion

Each bottle must be reconstituted followed by dilution with water to a final volume of 16 ounces and ingestion of 32 ounces of additional water as recommended is important to patient tolerance. Direct ingestion of the undiluted solution may increase the risk of nausea, vomiting, dehydration, and electrolyte disturbances.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs That May Increase Risks Due to Fluid and Electrolyte Abnormalities

Use caution when prescribing COLOTOSS Bowel Preparation Kit for patients with conditions, or who are using medications, that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, arrhythmias, and prolonged QT in the setting of fluid and electrolyte abnormalities. Consider additional patient evaluations as appropriate in patients taking these concomitant medications.

Potential for Altered Drug Absorption

Oral medication administered within one hour of the start of each COLOTOSS Bowel Preparation Kit dose may be flushed from the gastrointestinal tract, and the medication may not be absorbed properly.

4.6 Fertility, pregnancy and lactation

Pregnancy

Teratogenic effects: Pregnancy Category C. Animal reproduction studies have not been conducted with COLOTOSS Bowel Preparation Kit. It is also not known whether COLOTOSS Bowel Preparation Kit can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. COLOTOSS Bowel Preparation Kit should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when COLOTOSS Bowel Preparation Kit is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

Patients should be warned about engaging in activities requiring mental alertness eg, driving a car or operating appliances, machinery and others.

4.8 Undesirable effects

Very watery bowel movements are expected with this medication. Nausea, vomiting, bloating, or abdominal cramping/pain may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

This medication can cause your body to lose too much fluid (dehydration) and salt/minerals. Tell your doctor right away if you have any symptoms of dehydration or mineral loss, including: severe dizziness, fainting, fast/irregular heartbeat, severe vomiting, headache, seizure.

Tell your doctor right away if you have any serious side effects, including: signs of kidney problems (such as change in the amount of urine), severe stomach/abdominal pain, bloody stools, rectal bleeding.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

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

4.9 Overdose

Overdosage of more than the recommended dose of Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate Oral Solution may lead to severe electrolyte disturbances, as well as dehydration and hypovolemia, with signs and symptoms of these disturbances.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of Action

Sulfate salts provide sulfate anions, which are poorly absorbed. The osmotic effect of unabsorbed sulfate anions and the associated cations causes water to be retained within the gastrointestinal tract.

Pharmacodynamics

The osmotic effect of the unabsorbed ions, when ingested with a large volume of water, produces a copious watery diarrhea.

Pharmacokinetic properties

Absorption

After administration of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) in six healthy subjects, the time at which serum sulfate reached its highest point (Tmax) was approximately 17 hours after the first half dose or approximately 5 hours after the second dose.

Elimination

Serum sulfate concentrations declined with a half-life of 8.5 hours. The mean sulfate levels returned to baseline level by Day 6 after dose initiation. Fecal excretion was the primary route of sulfate elimination in healthy subjects.

Specific Populations

Hepatic and Renal Impairment

The disposition of sulfate after administration of another oral formulation of sodium sulfate (17.5 g), potassium sulfate (3.13 g), and magnesium sulfate (1.6 g) was studied in patients (N=6) with mildmoderate hepatic impairment (Child-Pugh grades A and B) and in patients (N=6) with moderate renal impairment (creatinine clearance of 30 to 49 mL/min). The renal impairment group had the highest serum sulfate AUC and Cmax, followed by the hepatic impairment group, and then by healthy subjects. The mean sulfate levels of all three groups returned to their respective baseline levels by Day 6 after dose initiation.

The systemic exposure of serum sulfate (AUC and Cmax) was similar between healthy subjects and patients with mild to moderate hepatic impairment. Urinary excretion of sulfate over 30 hours, starting after the first half dose, was similar between hepatically impaired patients and healthy subjects.

In patients with moderate renal impairment, mean AUC and Cmax were 54% and 44% higher than those in healthy subjects, respectively. Urinary excretion of sulfate over 30 hours, starting after the first half dose, was approximately 16% lower in moderate renal impairment patients than in healthy subjects.

5.3 Preclinical safety data

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of COLOTOSS Bowel Preparation Kit. Studies to evaluate the possible impairment of fertility or mutagenic potential of COLOTOSS Bowel Preparation Kit have not been performed.

Animal Toxicology and/or Pharmacology

The sulfate salts of sodium, potassium, and magnesium contained in COLOTOSS Bowel Preparation Kit were administered orally (gavage) to rats and dogs up to 28 days up to a maximum daily dose of 5 g/kg/day (approximately 0.9 and 3 times for rats and dogs, respectively, the recommended human dose of 44 g/day or 0.89 g/kg based on the body surface area). In rats, the sulfate salts caused diarrhea and electrolyte and metabolic changes, including hypochloremia, hypokalemia, hyponatremia, lower serum osmolality, and high serum bicarbonate. Significant renal changes included increased fractional sodium excretion, increased

urinary sodium and potassium excretion, and alkaline urine in both males and females. In addition, creatinine clearance was significantly decreased in females at the highest dose. No microscopic renal changes were seen. In dogs, the sulfate salts caused emesis, excessive salivation, excessive drinking of water, and abnormal excreta (soft and/or mucoid feces and/or diarrhea) and increased urine pH and sodium excretion.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Methyl Hydroxybenzoate, Sodium Propyl Hydroxybenzoate, Bronopol, Aspartame, Liquid Orange Flavour, Citric acid and Purified Water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30 C. Protect from direct sunlight & moisture.

6.5 Nature and contents of container

2 x 177 ml: 500 ml capacity bottle containing 177 ml solution and such 2 bottles are packed in a carton along with pack 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

Galaxy Pharmaceutical Ltd.
P.O.BOX 39107 - 00623,
Nairobi (Kenya).

Manufacturer

Saitech Medicare Pvt. Ltd.
Trilokpur road, Kala-Amb
Dist. Sirmor, Himachal Pradesh (INDIA).

8. Marketing Authorization Number

CTD11849

9. Date of first <registration> / renewal of the <registration>

13/07/2026

10. Date of Revision of the Text

13/07/2026