Summary of Product Characteristics

1. Name of the medicinal product

Polyethylene Glycol with Electrolytes for Oral Solution USP (PECOL POWDER)

2. Qualitative and quantitative composition

Each pack (145 g) contains:

Polyethylene Glycol 3350	USP	118.0 g
Sodium Chloride	BP	2.93 g
Potassium Chloride	BP	1.484 g
Sodium Bicarbonate	BP	3.370 g
Anhydrous Sodium Sulphate	BP	11.360 g

For full list of excipients see Section 6.1

3. Pharmaceutical form

Granules for Electrolytes for Oral Solution.
White Colour Free-Flowing Granules.

4. Clinical particulars

4.1 Therapeutic indications

Polyethylene Glycol with Electrolytes for Oral Solution is indicated for bowel cleansing prior to colonoscopy and barium enema X-ray examination in adults.

4.2 Posology and method of administration

HOW TO PREPARE

Step 1: Take a clean 2-liter container and empty the entire pack of PECOL (145 g) into it.

Step 2: Pour 1 Liter of water into the container and shake vigorously to dissolve PECOL. completely.

Step 3: Pour one more of water into the container to make this solution into 2 liters and then shake the container 3-4 times.

HOW TO DRINK

Step 1: Shake the solution well and pour it into a cup (approx. 200 ml).

Step 2: Drink 200 ml (one cup) at a time every 10-15 minutes so as to consume 1 liter of solution (five cups) in a maximum of 1-hour duration.

Step 3: Normally the first bowel movement may occur after about one hour from the start of drinking.

Step 4: Continue drinking the remaining PECOL. solution even after the start of the bowel movements (in the same manner as shown in Step 2).

The Bowel movement occurs several times (5-8 times). During the administration of remaining solution, you may however, stop drinking when the stool changes into water-like (colorless or yellowish) and without any solid matter which is an indication of lavage being completed.

4.3 Contraindications

Polyethylene Glycol with Electrolytes for Oral Solution is contraindicated in the following conditions:

-Gastrointestinal (GI) obstruction, ileus, or gastric retention
-Bowel perforation
-Toxic colitis or toxic megacolon
-Known allergy or hypersensitivity to any component of Polyethylene Glycol with Electrolytes for Oral Solution

4.4 Special warnings and precautions for use

Serious Fluid and Serum Chemistry Abnormalities

Advise patients to hydrate adequately before, during, and after the use of Polyethylene Glycol with Electrolytes for Oral Solution. Use caution in patients with congestive heart failure when replacing fluids. If a patient develops significant vomiting or signs of dehydration including signs of orthostatic hypotension after taking Polyethylene Glycol with Electrolytes for Oral Solution, consider performing post-colonoscopy lab tests (electrolytes, creatinine, and BUN) and treat accordingly. Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment. Fluid and electrolyte abnormalities should be corrected before treatment with Polyethylene Glycol with Electrolytes for Oral Solution.

In addition, use caution when prescribing Polyethylene Glycol with Electrolytes for Oral Solution for patients who have 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.

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 Polyethylene Glycol with Electrolytes for Oral Solution 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 Polyethylene Glycol with Electrolytes for Oral Solution 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 Polyethylene Glycol with Electrolytes for Oral Solution 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 post-colonoscopy 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 Polyethylene Glycol with Electrolytes for Oral Solution may increase this risk. 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 Polyethylene Glycol with Electrolytes for Oral Solution. If a patient experiences severe bloating, distention or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms abate. If gastrointestinal obstruction or perforation is suspected, appropriate studies should be performed to rule out these conditions before administration of Polyethylene Glycol with Electrolytes for Oral Solution. Use with caution in patients with severe active ulcerative colitis.

Aspiration
Use with caution in patients with impaired gag reflex, unconscious, or semiconscious patients, and patients prone to regurgitation or aspiration. Such patients should be observed during administration of Polyethylene Glycol with Electrolytes for Oral Solution, especially if it administered via nasogastric tube.

Not for Direct Ingestion
The contents of each packet must be diluted with water to a final volume of 1 gallon and ingestion of additional water is important to patient tolerance. Direct ingestion of the undissolved powder 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 Lead to Fluid and Electrolyte Abnormalities
Use caution when prescribing Polyethylene Glycol with Electrolytes for Oral Solution for patients 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 administration of Polyethylene Glycol with Electrolytes for Oral Solution may be flushed from the gastrointestinal tract and the medication may not be absorbed properly.

Stimulant Laxatives

Concurrent use of stimulant laxatives and Polyethylene Glycol with Electrolytes for Oral Solution may increase the risk of mucosal ulceration or ischemic colitis. Avoid use of stimulant laxatives (e.g., bisacodyl, sodium Pico sulfate) while taking Polyethylene Glycol with Electrolytes for Oral Solution.

4.6 Fertility, pregnancy and lactation

Pregnancy

Pregnancy Category C.

Animal reproduction studies have not been conducted with Polyethylene Glycol with Electrolytes for Oral Solution. It is also not known whether Polyethylene Glycol with Electrolytes for Oral Solution can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Polyethylene Glycol with Electrolytes for Oral Solution 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 Polyethylene Glycol with Electrolytes for Oral Solution is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

Not Applicable.

4.8 Undesirable effects

Reactions related to the gastrointestinal tract occur most commonly.

These reactions may occur as a consequence of expansion of the contents of the gastrointestinal tract, and an increase in motility due to the pharmacologic effects of Polyethylene Glycol with Electrolytes for Oral Solution. Mild diarrhea usually responds to dose reduction.

The frequency of the adverse effects is not known as it cannot be estimated from the available data.

System Organ Class	Adverse Event
Immune system disorders	Allergic reactions, including anaphylactic reactions, d*yspnea* and skin reactions (see below)
Skin and subcutaneous tissue disorders	Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema.
Metabolism and nutrition disorders	Electrolyte disturbances, particularly hyperkalemia and hypokalemia.
Nervous system disorders	Headache.
Gastrointestinal disorders	Abdominal pain, diarrhea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence and anorectal discomfort.
General disorders and administration site conditions	Peripheral oedema.

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 the relevant National Regulatory Authority.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of Action

The primary mode of action is thought to be through the osmotic effect of polyethylene glycol 3350 which causes water to be retained in the colon and produces a watery stool.

Pharmacodynamics

Polyethylene Glycol with Electrolytes for Oral Solution induces as diarrhea which rapidly cleanses the bowel, usually within four hours.

5.2 Pharmacokinetic properties

The pharmacokinetics of PEG3350 following administration of Polyethylene Glycol with Electrolytes for Oral Solution were not assessed. Available pharmacokinetic information for oral PEG3350 suggests that it is poorly absorbed.

5.3 Preclinical safety data

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term studies in animals have not been performed to evaluate carcinogenic potential of Polyethylene Glycol with Electrolytes for Oral Solution. Studies to evaluate the possible impairment of fertility or mutagenic potential of Polyethylene Glycol with Electrolytes for Oral Solution have not been performed.

6. Pharmaceutical particulars

6.1 List of excipients

Dry Orange Flavour, Aspartame and Mannitol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life: 24 months

6.4 Special precautions for storage:

Store below 30°C and protect from direct sunlight.

6.5 Nature and contents of container

145 gm pack.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder

Galaxy Pharmaceutical Ltd, 1st Floor, Doctors Park, 3rd Parkland Avenue,
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8. Marketing Authorization Number

H2012/CTD328/372

9. Date of first registration / renewal

6th September 2021

10. Date of revision of the text

12/08/2026