NDC 68220-133-01

Colyte® with Flavor Packs (peg-3350 & electrolytes for oral solution)
One Gallon

For Gastrointestinal Lavage **Rx only**

DESCRIPTION: Colyte® with flavor packs is a colon lavage preparation provided as water-soluble components for solution. In solution this preparation with one flavor pack delivers the following, in grams per liter.

Polyethylene glycol 3350	60.00
Sodium chloride	1.46
Potassium chloride	0.745
Sodium bicarbonate	1.68
Sodium sulfate	5.68
Flavor ingredients	0.851

When dissolved in sufficient water to make 1 gallon, the final solution contains 125 mEq/L sodium, 10 mEq/L potassium, 20 mEq/L bicarbonate, 80 mEq/L sulfate, 35 mEq/L chloride and 18 mEq/L polyethylene glycol 3350. The reconstituted solution is isosmotic and has a mildly salty taste. This preparation can be used without the flavor packs and is administered orally or via nasogastric tube.

Each orange flavor pack (3.22 g) contains hypromellose, natural and artificial orange powder, saccharin sodium, colloidal silicon dioxide. Each lemon lime flavor pack (3.22 g) contains, hypromellose, natural and artificial lemon lime powder, Prosweet® Powder Natural, saccharin sodium, colloidal silicon dioxide. Each cherry flavor pack (3.22 g) contains hypromellose, artificial cherry powder, saccharin sodium, colloidal silicon dioxide.

CLINICAL PHARMACOLOGY: Colyte® with flavor packs cleanses the bowel by induction of diarrhea. The osmotic activity of polyethylene glycol 3350, in combination with the electrolyte concentration, results in virtually no net absorption or excretion of ions or water.

INDICATIONS AND USAGE: Colyte with flavor packs is indicated for bowel cleansing prior to colonoscopy or barium enema X-ray examination.

CONTRAINDICATIONS:

Colyte is contraindicated in the following conditions:

- Gastrointestinal (GI) obstruction
- Bowel perforation
- Gastric retention
- Ileus
- Toxic colitis or toxic megacolon
- Known allergy or hypersensitivity to any component of Colyte [See How Supplied]

WARNINGS: Flavor packs are for use only in combination with the contents of the accompanying 1 gallon container. No other additional ingredients (e.g., flavorings) should be added to the solution. Colyte with flavor packs should be used with caution in patients with severe ulcerative colitis.

PRECAUTIONS:
General: Patients with impaired gag reflex, unconscious or semiconscious patients and patients prone to regurgitation or aspiration should be observed during the administration of Colyte® with flavor packs, especially if it is administered via nasogastric tube.

Serious Fluid and Serum Chemistry Abnormalities
Advise patients to hydrate adequately before, during, and after the use of Colyte. 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 Colyte, 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 Colyte.

In addition, use caution when prescribing Colyte 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, arrhythmia, 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 Colyte 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 seizures 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 with prescribing Colyte 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 Colyte 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 Colyte may increase the risk. The potential for mucosal ulcerations resulting from the bowel preparation should be considered when interpreting colonoscopy findings in patients with known or suspected 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 Colyte. Use 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 Colyte, especially if it is administered via nasogastric tube.

Not for Direct Ingestion
The contents of each jug must be diluted with water to final volume of 4 liters (4L) 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.

If gastrointestinal obstruction or perforation is suspected appropriate studies should be performed to rule out these conditions before administration of colyte® with flavor packs.

Patient Counseling Information: (see Medication Guide)
Colyte® with flavor packs produces a watery stool which cleanses the bowel prior to examination.

For best results, no solid food should be ingested during the 3 – 4 hour period prior to the initiation of Colyte with flavor packs administration. In no case should solid foods be eaten within 2 hours of drinking Colyte with flavor packs.

The rate of administration is 240 mL (8 fl. oz.) every 10 minutes. Rapid drinking of each portion is preferred rather than drinking small amounts continuously.

The first bowel movement should occur approximately one hour after the start of Colyte® with flavor packs administration.

Administration of Colyte with flavor packs should be continued until the watery stool is clear and free of solid matter. This normally requires the consumption of approximately 3 - 4 liters (3 - 4 quarts), although more or less may be required in some patients. The unused portion should be discarded.

Consume water or clear liquids during the bowel preparation and after completion of the bowel preparation up until 2 hours before the time of the colonoscopy.

Drug Interactions:

Drugs That May Increase Risks Due to Fluid and Electrolyte Abnormalities
Use caution when prescribing Colyte 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 seizures, arrhythmias, and prolonged QT in the setting of fluid and electrolyte abnormalities. Consider additional patient evaluations as appropriate (see Precautions) in patients taking these concomitant medications.

Potential for Altered Drug Absorption
Oral medication administered within one hour of the start of administration of Colyte may be flushed from the gastrointestinal tract and the medication may not be absorbed properly.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies to evaluate carcinogenesis or mutagenic potential or potential to adversely affect male or female fertility have not been performed.

Pregnancy: Category C. Animal reproduction studies have not been conducted with Colyte to evaluate the carcinogenic potential. It is not known whether Colyte can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Colyte 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 Colyte is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of Colyte in pediatric patients have not been established.

Geriatric Use: Published literature contains isolated reports of serious adverse reactions following the administration of PEG-ELS products in patients over 60 years of age. These adverse events include upper GI bleeding from Mallory-Weiss Tear, esophageal perforation, asystole, sudden dyspnea with pulmonary edema, and “butterfly-like” infiltrate on chest x-ray after vomiting and aspirating PEG.

ADVERSE REACTIONS: Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly

compared to rates in clinical studies of another drug and may not reflect the rates observed in practice.

Nausea, abdominal fullness and bloating are the most common adverse reactions (occurring in up to 50% of patients) to administration of Colyte. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient and usually subside rapidly. Isolated cases of urticaria, rhinorrhea, dermatitis, and rarely anaphylaxis, angioedema, tongue edema, and face edema have been reported which may represent allergic reactions.

To report suspected adverse events contact Meda Pharmaceuticals Inc. at toll free 1-888-317-0001 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION: Colyte with flavor packs can be administered orally or by nasogastric tube. Patients should fast at least 3 hours prior to administration. A one hour waiting period after the appearance of clear liquid stool should be allowed prior to examination to complete bowel evacuation. No foods except clear liquids should be permitted prior to examination after Colyte with flavor packs administration.

Oral: The recommended adult oral dose is 240 mL (8 fl. oz.) every 10 minutes (see **PRECAUTIONS, Information for Patients**). Lavage is complete when fecal discharge is clear. Lavage is usually complete after the ingestion of 3 - 4 liters (3 – 4 quarts).

Nasogastric Tube: Colyte with flavor packs is administered at a rate of 20 - 30 mL per minute (1.2 - 1.8 L/hour).

Preparation of Colyte with flavor packs Solution:
This preparation can be used with or without the flavor packs.

1. To add flavor, tear open one flavor pack at the indicated marking and pour contents into the bottle BEFORE reconstitution. Discard unused flavor packs.
2. SHAKE WELL to incorporate flavoring into powder.
3. Add tap water to FILL line. Replace cap tightly and mix or shake well until all ingredients have dissolved. (No other additional ingredients, e.g. flavorings, should be added to the solution.)

Note: If not using flavor packs, omit steps one and two above.

HOW SUPPLIED: Colyte with flavor packs is supplied in 1 gallon bottles with an attached package containing flavor packs. Each 1 gallon bottle contains polyethylene glycol 3350 227.10 g, sodium chloride 5.53 g, potassium chloride 2.82 g, sodium bicarbonate 6.36 g, sodium sulfate (anhydrous) 21.50 g. Each preparation is supplied in powdered form, for oral administration as a solution.

Colyte with flavor packs	1 gallon	NDC 68220-133-01

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F).

KEEP RECONSTITUED SOLUTION REFRIGERATED. USE WITHIN 48 HOURS. DISCARD UNUSED PORTION.

Rx only

Manufactured for:
Meda Pharmaceuticals Inc.
Somerset, NJ, USA

Manufactured by: Kremers Urban Pharmaceuticals Inc., Seymour, IN 47274

For Medical Inquiries,
Call toll-free 1-888-317-0001

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