NDC 68220-133-01

Note to pharmacist: Dispense bottle and all attached flavor packs to patient. Package insert enclosed. Remove before dispensing.

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. Accordingly, large volumes may be administered without significant changes in fluid and electrolyte balance.

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

CONTRAINDICATIONS: colyte® with flavor packs is contraindicated in patients known to be hypersensitive to any of the components. colyte® with flavor packs is contraindicated in patients with ileus, gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or toxic megacolon.

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.

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

Information for Patients:
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.

Drug Interactions:
Oral medication administered within one hour of the start of administration of colyte® with flavor packs may be flushed from the gastrointestinal tract and not absorbed.

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® with flavor packs, and it is not known whether colyte® with flavor packs can affect reproductive capacity or harm the fetus when administered to a pregnant patient. colyte® with flavor packs should be given to a pregnant patient only if clearly needed.

Pediatric Use:
Safety and effectiveness 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:
Nausea, abdominal fullness and bloating are the most frequent adverse reactions, occurring in up to 50% of patients. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient. Isolated cases of urticaria, rhinorrhea, dermatitis, and rarely anaphylaxis, angioedema, tongue edema, and face edema have been reported which may represent allergic reactions.

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:
ALAVEN Pharmaceutical LLC
Marietta GA USA
For Medical Inquiries,
Call toll-free 1-888-317-0001

NDC 68220-133-01

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(peg-3350 & electrolytes for oral solution)

One Gallon
For Gastrointestinal Lavage

Rx only

Instructions for Pharmacist:
Dispense bottle and all attached flavor packs to the patient.

Instructions for Patient:

1. colyte® with flavor packs can be used with or without the addition of one flavor pack.
   a) If you prefer an unflavored solution, discard the flavor packs and proceed to step 5.
   b) If you prefer a flavored solution, proceed to step 2.
2. Choose one of the flavor packs.
3. Tear open the selected flavor pack at the indicated marking and pour the contents into the bottle BEFORE adding any water. Discard the unused flavor packs.
4. SHAKE WELL to incorporate flavoring into the powder.
5. Add tap water to the top of the FILL line marked 1 Gallon. Recap tightly and mix or shake well until the powder has completely dissolved. No additional ingredients should be added to the solution.
6. Refrigerate the solution until ready to drink. Chilling improves the taste. Store no longer than 48 hours.
7. For best results, solid food should not be eaten during the 3 to 4 hour period before you start drinking the solution. Never eat solid food within 2 hours of drinking the solution.
8. Drink a glassful (8 oz.) of the solution every 10 minutes. It is best to drink the solution rapidly, rather than sipping slowly. Continue drinking a glassful every 10 minutes until your watery stool is clear and free of solid matter. This normally requires drinking 3 to 4 liters (3 to 4 quarts). The bottle should be empty (4 quarts consumed) or the remaining solution should be at or below the 1 quart mark (at least 3 quarts consumed).

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

Manufactured for:
ALAVEN Pharmaceutical LLC, Marietta, GA, USA

Manufactured by:
SCHWARZ PHARMA, Inc.
Milwaukee, WI 53201, USA

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

1 Gallon

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