

Lavage is complete when fecal discharge is clear. Lavage is usually complete after the ingestion of 3 to 4 liters.

NASOGASTRIC TUBE: GaviLyte-C with flavor pack is administered at the rate of 20 to 30 mL per minute (1.2 to 1.8 L/hour).

PREPARATION OF GaviLyte-C with flavor pack SOLUTION: This preparation can be used with or without the lemon flavor pack.

1. To add flavor, tear open lemon flavor pack at the indicated marking and pour contents into the bottle BEFORE reconstitution.
2. SHAKE WELL to incorporate flavoring into the 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 pack, omit steps one and two, above.

HOW SUPPLIED: GaviLyte-C with flavor pack is supplied in 4 liter bottles with an attached lemon flavor pack. Each 4 liter bottle contains polyethylene glycol-3350 240 g, sodium chloride 5.84 g, potassium chloride 2.98 g, sodium bicarbonate 6.72 g, sodium sulfate (anhydrous) 22.72 g. This preparation is supplied in powdered form, for oral administration as a solution.

GaviLyte-C with flavor pack 4 liter: NDC 43386-060-19
Store at 20° to 25°C (68° TO 77°F): excursions permitted between 15° to 30°C (59° to 86°F).

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

Manufactured by:
Novel Laboratories, Inc.
Somerset, NJ 08873, USA

Manufactured for:
Lupin Pharmaceuticals, Inc
Baltimore, MD 21202

SAP Code: 275344

Rev. 01/2024

When dissolved in sufficient water to make 4 liters, 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 an isosmotic solution, for oral administration, having mild salty taste. This preparation can be used without the flavor pack and is administered orally or via nasogastric tube.

Each lemon flavor pack (2 g) contains natural lemon flavor powder, saccharin sodium, maltodextrin.

CLINICAL PHARMACOLOGY: GaviLyte-C with flavor pack 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.

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GaviLyte™-C with Flavor Pack
(PEG-3350 (240 g) and Electrolytes
for Oral Solution, USP) with flavor pack

Rx Only

4 Liters

For Gastrointestinal Lavage

DESCRIPTION: GaviLyte-C with flavor pack is a white, colon lavage preparation provided as water-soluble components for solution. In solution this preparation with lemon flavor pack added 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	0.500



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Flavor ingredients	0.500



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

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

WARNINGS: Flavor pack is for use only in combination with the contents of the accompanying 4 liter container. No other additional ingredients (e.g., flavorings) should be added to the solution. Gavaltye-C with flavor pack 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 Gavaltye-C with flavor pack, 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 Gavaltye-C with flavor pack.

INFORMATION FOR PATIENTS: Gavaltye-C with flavor pack produces a watery stool which cleanses the bowel prior to examination.

For best results, no solid food should be ingested during the 3 to 4 hour period prior to the initiation of Gavaltye-C with flavor pack administration. In no cases should solid foods be eaten within 2 hours of drinking Gavaltye-C with flavor pack. 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 Gavaltye-C with flavor pack administration.

Administration of Gavaltye-C with flavor pack should be continued until the watery stool is clear and free of solid matter. This normally requires the consumption of approximately 3 to 4 liters (3 to 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 start of administration of Gavaltye-C with flavor pack may be flushed from the gastrointestinal tract and not absorbed.

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ORAL: The recommended adult oral dose is 240 mL (8 fl. Oz.) every 10 minutes (see INFORMATION FOR PATIENTS).

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