Lavage is complete when fecal discharge is clear. Lavage is

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

- To add flavor, tear open lemon flavor pack at the indicated marking and pour contents into the bottle REFORE reconstitution.
- 2. SHAKE WELL to incorporate flavoring into the powder.
- 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

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

Bx Only 4 Lite

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

For Gastrointestinal Lavage

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 isosmottic solution, for oral administration, having mild sally taste. This preparation can be used without the flavor pack and is administered orally or via nasogastric title colon.

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

CLINICAL PHARMACOLOGY: Gavil_yte-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.

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

- To add flavor, tear open lemon flavor pack at the indicated marking and pour contents into the bottle REFORE reconstitution.
- 2. SHAKE WELL to incorporate flavoring into the powder.
- 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

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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

Manufactured by:

Novel Laboratories, Inc. Somerset, NJ 08873, USA

Manufactured for:

Lupin Pharmaceuticals, Inc Baltimore MD 21202

SAP Code: 275344

Rev. 01/2024

GaviLyte™-C with Flavor Pack (PEG-3350 (240 g) and Electrolytes

for Oral Solution, USP) with flavor pack

Rx Only 4 Liters

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

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DRUG INTERACTIONS: Oral medication administered within one hour of start of administration of GaviLyte-C with flavor pack may be flushed from the gastrointestinal tract and not

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Studies to evaluate carcinogenic or mutage

FEFFILLY: Studies to evaluate carcinogenic or mutagenic or mutagenic or potential to potential to potential to adversely affect male or female fertility have not been performed.

PREGNANCY: Category C. Animal reproduction studies have not been conducted with Gavultyte-C with flavor pack, and it is not known whether Gaviltyte-C with flavor pack can affect to a pregnant patient. Gaviltyte-C with flavor pack should be up you go to a pregnant patient only it clearly needed.

PEDIATRIC USE: Safety and effectiveness in pediatric patients have not been established.

BEENATHIC USE: Published literature contains scoisted reports of serious adverse reactions following the commission of PEG-ELS products in patients over 60 years of age. These adverse events include upper GI bleeding from Mallony-Weiss Tear, esophagea perforation, asystolie, sudden dyspnes with pulmonany deams, and "burterdiy-like" infiltrate with pulmonany deams, and "burterdiy-like" infiltrate performance or chest X-ray after vomiting and aspirating PEG.

ADVERSE REACTIONS: Nauses, abdominal fullness and bloating are the most common adverse reactions, occurring in up to 50% of patients. Abdominal cramps, vomiting and enter the most frequently. These adverse reactions and irritation occur less frequently. These adverse reactions are transient. Isolated cases of urticaria, trinournea, dermaitits and rarely anaphylaxis, angloedema, fongue expressent allergior reactions.

DOSAGE AND ADMINISTRATION: Gavity/rec-C with flavor

DOSAGE AND ADMINISTRATION: Gavil_yle_V etc. with flavor backgrant by the administered orally or by nesogastric tube. Patients should start at least bruns prior to administration. A one hour waiting period after the sappearance of clear liquid stool should be allowed prior to examination to complete bowel evacuation. No foods except clear liquids should be emmitted prior to examination after david with flavor pack administration.

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

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

CONTRAINDICATIONS: GaviLyte-C with flavor pack is contraindisted in patients known to be hypersensitive to any off the components. GaviLyte-C with flavor pack is contraindicated in patients with ileus, gastrionitestinal obstruction, gastric retention, bowel perforation, toxic colitis

or taxic megacolons.

WARNINGS: Flavor pack is for use only in combination with inte configuration of the accompanying 4 liter container. No other additional ingredients (e.g., flavorings) should be added to the soution. Savil, the Coult of accompanying 4 liter contains used to be about on the soution. Savil, the Coult of several with flavor pack should be used with caution in patients with several coloring.

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 GaviLyte-C with flavor pack, especially if it is administration of GaviLyte-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 GaviLyte-C with flavor pack.

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

For best results, no soils food should be ingested during the for best results, no soils food should be ingested during the fiver peak schrinistation. In no case should solid foods be skien whitn is foure 10 dinnking Gavitye. — Will alwor pack for ministration is 204 m. (8 if o.z.) every 10 minutes. Rapid drinking of each portion is preferred rather mandering small should occur approximately not bound amovement should occur approximately not more more more contraction.

Administration of early, etc. with when the solid martined until the watery shool 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 start of administration of GaviLyDe-C with flavor pack may be flushed from the gastrointestinal tract and not

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF

FERTILITY: Studies to evaluate carcinogenic or mutagenic potential or potential to adversely affect male or female fertility have not been performed.

PREEMADY, Calegory, C. Animal eproduction adules have not been conducted with Gavil/yre-C with flavor pack, and it is not known whether Gavil/yre-C with flavor pack can affect reproductive capacity or harm the fleus when administered to a pregnant patient. Gavil/yre-C with flavor pack should be given to a pregnant patient only if clearly needed.

PEDIATIFIC USE: Safety and effectiveness in pediatric

GEMINTRIO USE: Published literature contains leolated reports of services adverse reactions following this administration of PECE-ELS products in patients over 60 years of age. These adverse events include upper GI bleeding from Mallony-Weiss Tear, expingates the profession, sudden dyspnes with pulmonary edema, and "burlediy-like" indilitate dyspnes with pulmonary edema, and "burlediy-like" indilitate to no cheest X-ray after vomitting and aspirating PEC.

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DOSGE ALM DANINISTENSION: Gavilyte-D (Avgih flavor DOSGE ALM) MAID IN Gavilyte (Avgih Gavilyte) about a three goesen (Avgih Gavilyte) and a three goesen (Avgih Gavilyte) and

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CONTRAINDICATIONS: GaviLyte-C with flavor pack is contraindicated in patients known to be hypersensitive to any of the components. GaviLyte-C with flavor pack is components. GaviLyte-C with flavor pack is contraindicated in patients with ileus, gastrointestinal

or toxic megacolon.

WARNINGS: Flavor pack is for use only in combination with the contents of the accompanying 4 lier container. No other additional ingredients (e.g., flavorings) should be aded to the solution. GavilLyte-C with flavor pack should be used with the solution. GavilLyte-C with flavor pack should be used with the solution in patients with severe ulcerative collitis.

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PRECAUTIONS: General: Patients with impaired gag reflex, unconscious or semiconscious patients and patients prone to requiritation of GavilLyte-C with flavor pack, especially if it is administration of GavilLyte-C with flavor pack, especially if it is definited to the patients of the p

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

Per best results, no solid food should be ingested during the 3 to 4 hour period prior to the initiation of GaviLyte-C with flavor pack administration, in no case should solid foods be esten within 2 hours of drinking GaviLyte-C with flavor pack line rate of administration is 240 mL (8 fl. cx.) every 10 km minutes. Rapid drinking of aech portion is preferred rather minutes. Rapid drinking of aech portion is preferred rather minutes. Rapid drinking of aech portion is preferred rather movement should occur approximately one hour after the start of GaviLyte-C with flavor pack administration. Administration of GaviLyte-C with flavor pack should be

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