GAVILYTE - C TM- polyethylene glycol-3350 and electrolytes with flavor pack powder, for solution
Lupin Pharmaceuticals,Inc.

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

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	240.00
Sodium chloride	5.84
Potassium chloride	6.72
Sodium bicarbonate	2.98
Sodium sulfate	22.72
Flavor ingredients	0.500

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 lemon 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.

INDICATIONS AND USAGE

GaviLyte- 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 contraindicated in patients known to be hypersensitive to any of the components. GaviLyte- 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. GaviLyte- 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 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 examination.

For 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 eaten within 2 hours of drinking GaviLyte- 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 GaviLyte- C with flavor pack administration.

Administration of GaviLyte- 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 GaviLyte- C with flavor pack may be flushed from the gastrointestinal tract and not absorbed.

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.

PREGNANCY

Category C. Animal reproduction studies have not been conducted with GaviLyte- C with flavor pack, and it is not known whether GaviLyte- C with flavor pack can affect reproductive capacity or harm the fetus when administered to a pregnant patient. GaviLyte- C with flavor pack 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

GaviLyte- C with flavor pack 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 GaviLyte- C with flavor pack administration.

ORAL: The recommended adult oral dose is 240 mL (8 fl. oz.) every 10 minutes (see INFORMATION FOR PATIENTS). 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 a 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 4liter: 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.

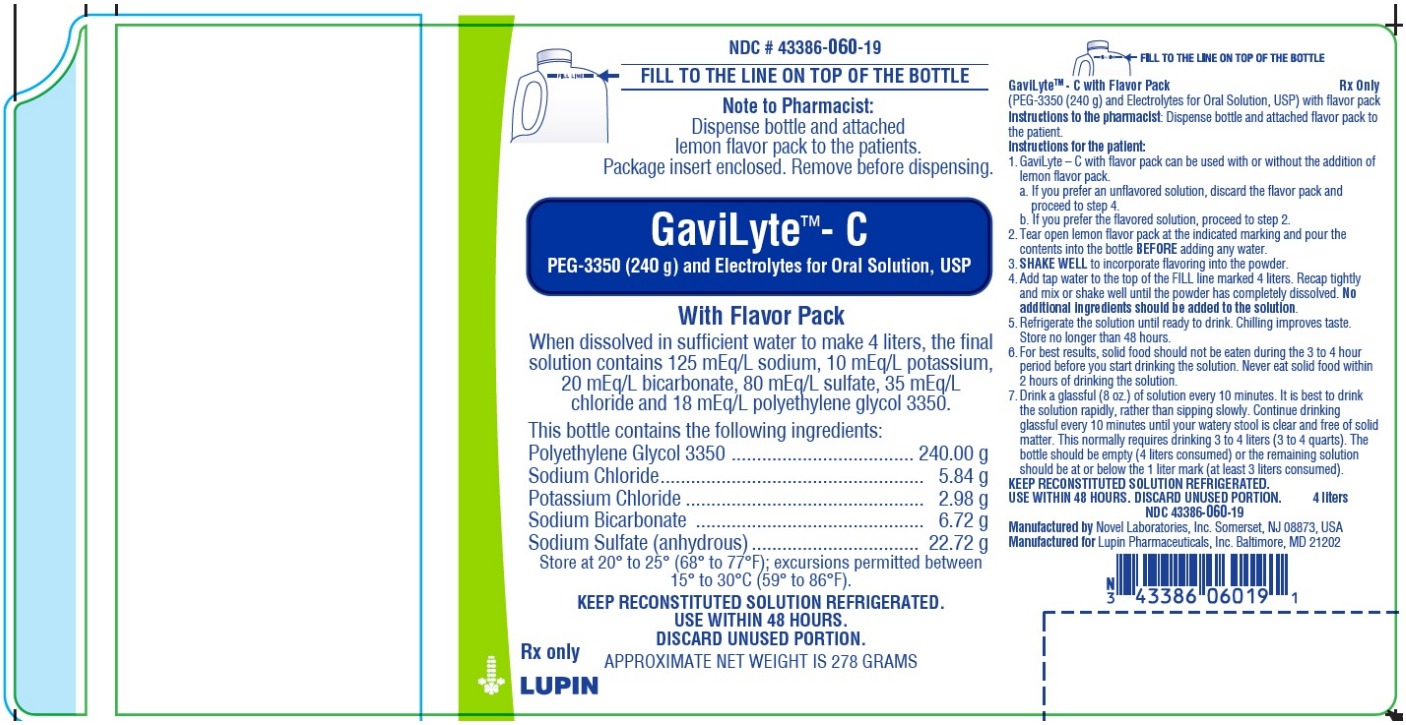
Baltimore, MD 21202

LA0601900203

Rev. 09/2017

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Gavilyte-C with Flavor Pack (PEG-3350 (240g) and electrolytes for oral solution, USP) with flavor pack



Lemon Flavor Pack

ATTENTION PHARMACIST:
Dispense attached pack to the patient.

Lemon
flavor pack

FOR USE ONLY IN COMBINATION WITH THE ACCOMPANYING CONTAINER.

LUPIN net wt. 2 g

1 43386-20402 3
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Baltimore, MD 21202

GAVILYTE - C TM

polyethylene glycol-3350 and electrolytes with flavor pack powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43386-060
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	240 g in 278.26 g
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	5.84 g in 278.26 g
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	2.98 g in 278.26 g
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	6.72 g in 278.26 g
SODIUM SULFATE ANHYDROUS (UNII: 36KCS0R750) (SODIUM SULFATE ANHYDROUS - UNII:36KCS0R750)	SULFATE ION	22.72 g in 278.26 g

Inactive Ingredients	
Ingredient Name	**Strength**

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	LEMON	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43386-060-19	278.26 g in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090186	01/06/2009	

Labeler - Lupin Pharmaceuticals,Inc. (089153071)

Registrant - Novel Laboratories, Inc. (793518643)

Establishment

Name	Address	ID/FEI	Business Operations
Novel Laboratories, Inc.		793518643	MANUFACTURE(43386-060) , ANALYSIS(43386-060) , PACK(43386-060)

Revised: 11/2017 Lupin Pharmaceuticals,Inc.