GAVILYTE-H AND BISACODYL- polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride and bisacodyl delayed-release tablet
Lupin Pharmaceuticals, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use GaviLyte-H and Bisacodyl safely and effectively. See full prescribing information for GaviLyte-H and Bisacodyl.

GaviLyte-H and Bisacodyl (Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride and Bisacodyl Delayed release Tablet) KIT for ORAL use.

Initial U.S. Approval: 2004

INDICATIONS AND USAGE

GaviLyte - H and bisacodyl delayed-release tablet, USP is a combination of PEG-3350, an osmotic laxative and bisacodyl, a stimulant laxative, indicated for cleansing of the colon as a preparation for colonoscopy in adults (1)

DOSAGE AND ADMINISTRATION

See FULL PRESCRIBING INFORMATION for complete dosing and administration instructions (2)

- No solid food or milk (clear liquids only) should be consumed on the day of the preparation.
- Take one 5 mg bisacodyl tablet with water. Do NOT chew or crush.
- Dissolve the GaviLyte - H powder in 2 liters of water.
- Wait for a bowel movement (or maximum of 6 hours) then drink all the GaviLyte - H solution at a rate of 8 ounces every 10 minutes.
- Consume only clear liquids until the colonoscopy.

DOSAGE FORMS AND STRENGTHS

- One 5 mg bisacodyl delayed-release tablet, USP (3)
- One 2 liter GaviLyte - H bottle with powder for reconstitution (3)

CONTRAINDICATIONS

- Gastrointestinal (GI) obstruction (4)
- Bowel perforation (4)
- Toxic colitis or toxic megacolon (4)
- Gastric retention (4)
- Ileus (4)

WARNINGS AND PRECAUTIONS

- Risk of fluid and electrolyte abnormalities, arrhythmias, seizures and renal impairment – assess concurrent medications and consider testing in some patients (5.1, 5.2, 5.3, 5.4)
- Patients with renal impairment – use caution, ensure adequate hydration and consider testing (5.3)
- Ischemic colitis has been reported (5.5)
- Suspected GI obstruction or perforation – rule out the diagnosis before administration (5.6)
- Patients at risk for aspiration – observe during administration (5.7)

ADVERSE REACTIONS

Most common adverse reactions (>3%) are overall discomfort, abdominal fullness, abdominal cramping, nausea, and vomiting, (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Novel Laboratories, Inc. at 908-603-6000 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

DRUG INTERACTIONS

- Some drugs (e.g., diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, or non-steroidal anti-inflammatory drugs) increase risk due to fluid and electrolyte changes (7.1)
- Oral medication administered within one hour of the start of drinking GaviLyte - H might not be absorbed fully. (7.2)
- Do not take the bisacodyl tablet within one hour of taking antacid (7.3)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 8/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS & USAGE
2 DOSAGE & ADMINISTRATION
3 DOSAGE FORMS & STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Serious Fluid and Serum Chemistry Abnormalities
5.2 Seizures
5.3 Renal Impairment
5.4 Cardiac Arrhythmias
5.5 Ischemic Colitis
5.6 Patients with Significant Gastrointestinal Disease
5.7 Aspiration
6 ADVERSE REACTIONS
6.1 Clinical Studies Experience
6.2 Postmarketing Experience
7 DRUG INTERACTIONS
7.1 Drugs That May Increase Risks of Fluid and Electrolyte Abnormalities
7.2 Potential for Altered Drug Absorption
7.3 Interaction with Antacids
8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
8.3 Nursing Mothers
8.4 Pediatric Use
8.5 Geriatric Use
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 PharmacoKinetics
13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS & USAGE

GaviLyte - H and bisacodyl delayed-release tablet, USP is indicated for cleansing of the colon as a preparation for colonoscopy in adults.

2 DOSAGE & ADMINISTRATION

The recommended GaviLyte - H and bisacodyl delayed-release tablet, USP oral dosage regimen for adults on the day prior to colonoscopy is as follows:

- No solid food or milk (clear liquids only) should be consumed on the day of the preparation.
- Take one 5 mg bisacodyl delayed-release tablet, USP with water. Do NOT chew or crush the tablet.
- No antacids should be taken within one hour of taking the bisacodyl delayed-release tablet, USP.
- Prepare the GaviLyte - H solution according to the instructions on the kit.
- Add flavor pack of choice (if applicable) to the 2 liter container.
- No additional ingredients (other than flavor packs provided) should be added to the solution.
- Prepare the GaviLyte - H solution by filling the container to the 2 liter mark with water. Cap the container. Shake to dissolve the powder.
- Wait for a bowel movement (or maximum of 6 hours) then drink the 2 liter GaviLyte - H solution at a rate of 8 ounces every 10 minutes. Drink all of the solution.
- If you have abdominal distention or discomfort, stop drinking the GaviLyte - H solution temporarily or drink each portion at longer intervals until your symptoms improve.
- Consume only clear liquids after taking the GaviLyte - H solution until your colonoscopy.

3 DOSAGE FORMS & STRENGTHS

- One pink, round, enteric coated 5 mg bisacodyl delayed-release tablet, USP, de-bossed with “N1” on one side and plain on the other side.
- One 2 liter GaviLyte - H bottle with powder for reconstitution

4 CONTRAINDICATIONS

The GaviLyte - H and bisacodyl delayed-release tablet, USP is contraindicated in the following conditions:

- Gastrointestinal (GI) obstruction
- Bowel perforation
- Toxic colitis and toxic megacolon
- Gastric retention
- Ileus

5 WARNINGS AND PRECAUTIONS

5.1 Serious Fluid and Serum Chemistry Abnormalities

Advise all patients to hydrate adequately before, during, and after the use of GaviLyte - H and bisacodyl delayed-release tablet, USP. If a patient develops significant vomiting or signs of dehydration after taking GaviLyte - H and bisacodyl delayed-release tablet, USP,

consider performing post-colonoscopy lab tests (electrolytes, creatinine, and BUN). Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures and renal impairment.

Patients with electrolyte abnormalities should have them corrected before treatment with GaviLyte - H and bisacodyl delayed-release tablet, USP. In addition, use caution when prescribing GaviLyte - H and bisacodyl delayed-release tablet, USP 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 seizure, arrhythmias, and renal impairment.[See Drug Interactions (7.1)]

5.2 Seizures

There have been reports of generalized tonic-clonic seizures with the use of large volume (4 liter) PEG-based colon preparation products in patients with no prior history of seizures. The seizure 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 when prescribing the GaviLyte - H and bisacodyl delayed-release tablet, USP for patients with a history of seizures and in patients at risk of seizure, such as patients taking medications that lower the seizure threshold (e.g., tricyclic antidepressants), patients withdrawing from alcohol or benzodiazepines, patients with known or suspected hyponatremia, or patients using concomitant medications (such as diuretics) that increase the risk of electrolyte abnormalities. Monitor baseline and post-colonoscopy laboratory tests (sodium, potassium, calcium, creatinine, and BUN) in these patients.

5.3 Renal Impairment

Patients with impaired water handling who experience severe vomiting should be closely monitored including measurement of electrolytes (sodium, potassium, calcium, BUN and creatinine). Use caution when prescribing GaviLyte - H and bisacodyl delayed-release tablet, USP 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.

5.4 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 GaviLyte - H and bisacodyl delayed-release tablet, USP 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.

5.5 Ischemic Colitis

There have been reports of ischemic colitis in patients with use of GaviLyte - H and 20 mg bisacodyl delayed-release tablet, USP and GaviLyte - H and 10 mg bisacodyl delayed-release tablet, USP. If patients develop severe abdominal pain or rectal bleeding, patients should be evaluated as soon as possible.

5.6 Patients with Significant Gastrointestinal Disease

If gastrointestinal obstruction or perforation is suspected, perform appropriate diagnostic studies to rule out these conditions before administering GaviLyte - H and bisacodyl delayed-release tablet, USP

Use with caution in patients with severe active ulcerative colitis.

5.7 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 the GaviLyte - H and bisacodyl delayed-release tablet, USP solution.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

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.

In a clinical study of GaviLyte - H and (5 mg vs. 10 mg) bisacodyl delayed-release tablet, USP, overall discomfort, abdominal fullness, abdominal cramping, nausea, and vomiting, were the most common adverse reactions (>3%). The data in Table 1 reflects the 154 patients that received GaviLyte - H and 5 mg bisacodyl tablet vs. the 154 patients that received GaviLyte - H and 10 mg bisacodyl tablets. The GaviLyte - H and 5 mg bisacodyl delayed-release tablet, USP population was 29-87 years of age, 49% male, 51% female, 13% African American, 83% White, 5% Hispanic requiring a colonoscopy. The demographics of the comparator group were similar.

Table 1: Adverse Reactions Observed in at Least 3% of Randomized Patients

	GaviLyte - H and 5 mg Bisacodyl Delayed-release Tablet, USP(N=154)]	GaviLyte - H and 10 mg Bisacodyl Delayed-release Tablet, USP(N=154)
Overall Discomfort	57%	66%
Abdominal fullness	40%	53%
Abdominal cramping	38%	46%
Nausea	34%	42%
Vomiting	10%	7%

6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of GaviLyte - H and bisacodyl delayed-release tablet, USP. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Allergic Reactions:
Cases of urticaria, rhinorrhea, dermatitis and anaphylactic reactions have been reported with PEG-based products.

Gastrointestinal:
There are isolated reports of serious post-marketing events following the administration of PEG-based products in patients over 60 years of age. These adverse reactions include upper GI bleeding from a Mallory-Weiss tear, esophageal perforation, asystole, and acute pulmonary edema after vomiting and aspirating the PEG-based solution. In addition, during administration of 4 liters of PEG-3350 colon cleansing preparation the following serious adverse reactions were seen: two deaths in end stage renal failure patients who developed diarrhea, vomiting and dysnatremia *[*see Warnings and Precautions (5.3) *].*

Ischemic colitis has been reported with use of of GaviLyte - H and 20 mg and 10 mg bisacodyl delayed-release tablets, USP for colon preparation prior to colonoscopy. However, a causal relationship between these ischemic colitis cases and the use of GaviLyte - H and bisacodyl delayed-release tablets, USP has not been established.

Neurologic:
There have been reports of generalized tonic-clonic seizures associated with use of large volume (4 liter) PEG-based colon preparation products in patients with no prior history of seizures. Cases of dizziness and syncope have been reported [see Warnings and Precautions (5.1)] .

7 DRUG INTERACTIONS

7.1 Drugs That May Increase Risks of Fluid and Electrolyte Abnormalities

Use caution when prescribing GaviLyte - H and bisacodyl delayed-release tablet, USP 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 seizure, arrhythmias, and prolonged QT in the setting of fluid and electrolyte abnormalities. Consider additional patient evaluations as appropriate [see Warnings and Precautions (5.1)] in patients taking these concomitant medications.

7.2 Potential for Altered Drug Absorption

Oral medication administered within one hour of the start of administration of GaviLyte - H solution may be flushed from the GI tract and the medication may not be absorbed completely.

7.3 Interaction with Antacids

Do not take the bisacodyl delayed-release tablet within one hour of taking an antacid.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C animal reproduction studies have not been conducted. It is not known whether GaviLyte - H and bisacodyl delayed-release tablet, USP can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. GaviLyte - H and bisacodyl delayed-release tablet, USP should be given to a pregnant or nursing woman only if clearly needed.

8.3 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 GaviLyte - H and bisacodyl delayed-release tablet, USP is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients has not been established.

8.5 Geriatric Use

Of the 148 patients who took GaviLyte - H and 5 mg bisacodyl delayed-release tablet, USP in clinical trials, 42 (28%) were 65 years of age or older, while 10 (7%) were 75 years of age or older. The rates of success appear to be lower in patients 65 years and older [see Clinical Studies (14)] .

10 OVERDOSAGE

Using more than the recommended dosage of bisacodyl in conjunction with GaviLyte - H solution increases the frequency of common adverse events and may increase the risk of ischemic colitis [see Warnings and Precautions (5.5)] .

11 DESCRIPTION

GaviLyte - H and bisacodyl delayed-release tablet, USP consists of PEG-3350, an osmotic laxative and bisacodyl, a stimulant laxative. Each GaviLyte - H and 5 mg bisacodyl delayed-release tablet, USP (Polyethylene glycol (PEG) 3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablet) consists of one 2 liter bottle of GaviLyte – H (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) powder for reconstitution and one 5 mg bisacodyl, delayed-release tablet, USP.

- **Bisacodyl delayed-release tablet, USP:** Each pink, round, enteric coated bisacodyl delayed-release tablet, USP (debossed “N1”) contains 5 mg of bisacodyl, USP ($C_{22}H_{19}NO_4$) with a molecular weight of 361.40. Inactive ingredients include lactose (anhydrous) NF, microcrystalline cellulose NF, croscarmellose sodium NF, magnesium stearate NF, methacrylic acid copolymer, talc, titanium dioxide, triethyl

citrate, D&C red # 27/phloxine aluminum lake, colloidal anhydrous silica, sodium bicarbonate, sodium lauryl sulfate, FD&C blue # 2/indigo carmine aluminum lake and FD&C yellow # 6/sunset yellow FCF aluminum lake. The bisacodyl delayed-release tablet, USP is administered orally prior to drinking the GaviLyte - H [see Dosage and Administration (2)] .

- **GaviLyte – H (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution):** A white powder for reconstitution containing 210 grams of PEG-3350, 2.86 grams of sodium bicarbonate, 5.6 grams of sodium chloride, 0.74 grams of potassium chloride and 2 grams of flavoring ingredients (if applicable). Flavor Packs are available in Cherry (containing artificial cherry flavor powder, maltodextrin and sodium saccharin), Lemon (containing natural lemon flavor powder, maltodextrin and sodium saccharin), and Orange (containing natural and artificial orange flavor powder, maltodextrin and sodium saccharin). This preparation can be used without the addition of a Flavor Pack. When dissolved in water to a volume of 2 liters, the GaviLyte - H solution is isosmotic, clear, and colorless. The GaviLyte - H solution is administered orally after taking the one bisacodyl delayed-release tablet, USP [see Dosage and Administration (2)] .

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Polyethylene glycol (PEG), which is an osmotic agent, causes water to be retained within the gastrointestinal tract.

Bisacodyl is hydrolyzed by intestinal brush border enzymes and colonic bacteria to form an active metabolite [bis-(p-hydroxyphenyl) pyridyl-2 methane; (BHPM)] that acts directly on the colonic mucosa to produce colonic peristalsis.

12.2 Pharmacodynamics

The stimulant laxative effect of bisacodyl, together with the osmotic effect of the unabsorbed PEG when ingested with a large volume of water, produces watery diarrhea.

12.3 PharmacoKinetics

When taken orally, PEG 3350 is minimally absorbed.

Bisacodyl, which is a prodrug, is converted to its active metabolite BHPM by intestinal brush border enzymes and colonic bacteria. The pharmacokinetics of bisacodyl following oral administration of the bisacodyl tablet has not been adequately characterized.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of GaviLyte - H and bisacodyl delayed-release tablet, USP. Studies to evaluate its potential for impairment of fertility or its mutagenic potential have not been performed.

14 CLINICAL STUDIES

The colon cleansing efficacy of GaviLyte - H and bisacodyl delayed-release tablet, USP (with 5 mg of bisacodyl) was evaluated in a randomized, single blind (endoscopist only), active-controlled, multicenter study. In this study, 293 adult patients were included in the efficacy analysis. Patients ranged in age from 19 to 87 years old (mean age 55 years old) with 55% female and 45% male patients. Race was distributed as follows: 83% White, 12% African American, 8% Hispanic or Latino, and 4% other.

Patients were randomized to one of the following two colon preparations: 1) GaviLyte - H and bisacodyl delayed-release tablet, USP [10 mg of bisacodyl tablets were given at noon on the day before colonoscopy followed by 2 liters of GaviLyte - H (after the first bowel movement or maximum of 6 hours)] at a rate of 8 ounces every 10 minutes and 2) a modified GaviLyte - H and bisacodyl delayed-release tablet, USP [containing a 5 mg bisacodyl tablet given at noon on the day before colonoscopy followed by 2 liters of GaviLyte - H (after the first bowel movement or maximum of 6 hours)] at a rate of 8 ounces every 10 minutes.

Patients were instructed to refrain from solid food and to have clear liquids on the day before colonoscopy. In addition, patients were instructed to consume nothing by mouth, except clear liquids, from the time the preparation was completed until after the colonoscopy was completed.

The primary efficacy endpoint was the proportion of patients with successful colon cleansing (assessed by the colonoscopists), see Table 2 below. Successful colon cleansing was defined as preparations that were graded excellent (no more than small bits of adherent feces/fluid) or good (small amounts of feces or fluid not interfering with the exam) by the colonoscopist.

Table 2: Proportion of Patients with Successful Colon Cleansing

	GaviLyte - H and 5 mg Bisacodyl Delayed-release Tablet, USP (H5)		GaviLyte - H and 10 mg Bisacodyl Delayed-release Tablet, USP (H10)		Difference between treatment groups(H5 - H10)	
	% (n/N)	Two-sided 95% CI [1]	% (n/N)	Two-sided 95% CI [1]	Percent Difference %	Two-sided 95% CI for Percent Difference
All Patients	78 (114/147)	(69.9, 84.0)	80 (117/146)	(72.7, 86.3)	-2.0	(-11.9, 6.8)

[1]Confidence Interval (CI) for within treatment percent success is from an exact Chi Square test.

The proportion of patients with successful colon cleansing was similar between treatment groups. No differences in response rates by gender or race were noted in the GaviLyte - H and 5 mg bisacodyl group. In patients ≥ 65 years of age treated with the GaviLyte - H and 5 mg bisacodyl delayed-release tablet, USP the proportion with successful colon cleansing was 67% (n=28/42)[95% CI: (50.5, 80.4)].

16 HOW SUPPLIED/STORAGE AND HANDLING

Each GaviLyte - H and bisacodyl delayed-release tablet, USP contains:

One 5 mg bisacodyl delayed-release tablet, USP: pink, round, enteric coated, debossed “N1” on one side and plain on the other in a blister strip.

One 2 liter bottle of GaviLyte – H (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) powder for reconstitution containing 210 grams of polyethylene glycol (PEG) 3350, 2.86 grams of sodium bicarbonate, 5.6 grams of sodium chloride, 0.74 grams of potassium chloride, and 2 gram of flavoring ingredients (if applicable). After adding 2 liters of water, the reconstituted GaviLyte - H solution (clear and colorless) contains 31.3 mmol/L of PEG-3350, 65 mmol/L of sodium, 53 mmol/L of chloride, 17 mmol/L of bicarbonate and 5 mmol/L of potassium.

GaviLyte - H and bisacodyl delayed-release tablet, USP with Flavor Packs contain 3 packs (2 gram each Cherry, Lemon, and Orange flavors) **NDC 43386-071-83.**

Storage:
Store at 20-25°C (68-77°F). Excursions permitted between 15-30°C (59-86°F). The reconstituted GaviLyte – H solution, which may be refrigerated, should be used within 48 hours.

17 PATIENT COUNSELING INFORMATION

See Medication Guide

Information for Patients

- Ask patients to let you know if they have trouble swallowing or are prone to regurgitation or aspiration.
- Tell patients not to take other laxatives while they are taking GaviLyte - H and bisacodyl delayed-release tablet , USP
- Tell patients that if they experience severe bloating, distention or abdominal pain, the administration of the solution should be slowed or temporarily discontinued until the symptoms abate. Advise patients to report these events to their health care provider.
- Advise patients that if they have hives, rashes, or any allergic reaction, they should discontinue the medication and contact their health care provider. Medication should be discontinued until they speak to their physician.
- Instruct patients to contact their healthcare provider if they develop signs and symptoms of dehydration. *[see Warnings and Precautions (5.1)].*
- Inform patients that oral medication administered within one hour of the start of administration of GaviLyte - H may be flushed from the GI tract and the medication may not be absorbed completely.

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

Manufactured for:

GAVIS Pharmaceuticals, LLC

Somerset, NJ 08873

PI0701700201
Iss. 12/2014

Medication Guide

GaviLyte - H (GAV-ee-LITE-H) and Bisacodyl (BIS-a-CO-dil)Delayed-Release Tablet, USP.

(PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablet, USP)

Read this Medication Guide before you start taking GaviLyte - H and bisacodyl delayed-release tablet, USP. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about GaviLyte - H and bisacodyldelayed-release tablet, USP?

GaviLyte - H and bisacodyl delayed-release tablet, USP and other osmotic bowel preparations can cause serious side effects, including: Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood. These changes can cause:

- seizures. This can happen even if you have never had a seizure.
- kidney problems
- abnormal heartbeats that can cause death

Your chance of having fluid loss and changes in body salts with GaviLyte - H and bisacodyl delayed-release tablet, USPis higher if you:

- have heart problems
- have kidney problems
- take water pills or non-steroidal anti-inflammatory drugs (NSAIDS)

Tell your healthcare provider right away if you have any of these symptoms of a loss of too much body fluid (dehydration) while taking GaviLyte - H and bisacodyldelayed-release tablet, USP:

- dizziness
- urinating less often than normal
- headache

See "What are the possible side effects of GaviLyte - H and bisacodyl delayed-release tablet, USP?" for more information about side effects.

What is GaviLyte - H and bisacodyl delayed-release tablet, USP?

GaviLyte - H and bisacodyl delayed-release tablet, USP is a prescription medicine used by adults to clean the colon before a colonoscopy. GaviLyte - H and bisacodyl delayed-release tablet, USP cleans your colon by causing you to have diarrhea. Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy. It is not known if GaviLyte - H and bisacodyl delayed-release tablet, USP is safe and effective in children.

Who should not take GaviLyte - H and bisacodyldelayed-release tablet, USP?

Do not take GaviLyte - H and bisacodyl delayed-release tablet, USP if your healthcare provider has told you that you have:

- a blockage in your bowel (obstruction)
- an opening in the wall of your stomach or intestine (bowel perforation)
- problems with food and fluid emptying from your stomach (gastric retention)
- a very dilated intestine (bowel)

- an allergy to any of the ingredients in GaviLyte - H and bisacodyl delayed-release tablet, USP. See the end of this leaflet for a complete list of ingredients in GaviLyte - H and bisacodyl delayed-release tablet, USP.

What should I tell my healthcare provider before taking GaviLyte - H and bisacodyldelayed-release tablet, USP?

Before you take GaviLyte - H and bisacodyldelayed-release tablet, USP tell your healthcare provider if you:

- have heart problems
- have stomach or bowel problems
- have ulcerative colitis
- have problems with swallowing or gastric reflux
- have a history of seizures
- are withdrawing from drinking alcohol
- have a low blood salt (sodium) level
- have kidney problems
- have any other medical conditions
- are pregnant. It is not known if GaviLyte - H and bisacodyl delayed-release tablet, USP will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if GaviLyte - H and bisacodyl delayed-release tablet, USP passes into your breast milk. You and your healthcare provider should decide if you will take GaviLyte - H and bisacodyl delayed-release tablet, USP while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

GaviLyte - H and bisacodyl delayed-release tablet, USP may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of GaviLyte - H and bisacodyl delayed-release tablet, USP.

Especially tell your healthcare provider if you take:

- medicines for blood pressure or heart problems
- medicines for kidney problems
- medicines for depression
- water pills (diuretics)
- non-steroidal anti-inflammatory medicines (NSAID) pain medicines
- laxatives
- antacids

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure if you are taking any of the medicines listed above. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take GaviLyte - H and bisacodyldelayed-release tablet, USP?

See the Patient Directions on the outer product carton for dosing instructions. You must read, understand, and follow these instructions to take GaviLyte - H and bisacodyldelayed-release tablet, USPthe right way.

- Take GaviLyte - H and bisacodyl delayed-release tablet, USP exactly as your healthcare provider tells you to take it.

- Do not take other laxatives while taking GaviLyte - H and bisacodyl delayed-release tablet, USP.
- Do not take antacids within 1 hour of taking the bisacodyl tablet.
- Do not chew or crush the bisacodyl tablet. Take the tablet with water.
- Do not eat solid foods while taking GaviLyte - H and bisacodyl delayed-release tablet, USP. Only clear liquids are allowed while taking and after taking GaviLyte - H and bisacodyl delayed-release tablet, USP until your colonoscopy.
- Stop drinking GaviLyte - H temporarily or allow for longer time between each dose if you have stomach discomfort, pain or bloating until your symptoms improve.
- Stop taking GaviLyte - H and bisacodyl delayed-release tablet, USP and call your healthcare provider right away if you develop hives or a rash. These may be signs of an allergic reaction.

What are the possible side effects of GaviLyte - H and bisacodyldelayed-release tablet, USP?

GaviLyte - H and bisacodyl delayed-release tablet, USP can cause serious side effects, including:

- **See “What is the most important information I should know about GaviLyte - H and bisacodyl delayed-release tablet, USP?”**
- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take GaviLyte - H and bisacodyl delayed-release tablet, USP to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
- vomiting
- nausea
- bloating
- dizziness
- stomach (abdominal) cramping
- headache
- urinate less than usual
- trouble drinking clear liquid
- **heart problems. GaviLyte - H and bisacodyldelayed-release tablet, USP may cause irregular heartbeats.**
- **seizures**
- **decreased blood flow to the intestine (ischemic colitis).** There have been reports of ischemic colitis in people who have taken GaviLyte - H and bisacodyl delayed-release tablet, USP at higher doses. Tell your healthcare provider right away if you have severe stomach (abdominal) pain or rectal bleeding. These may be symptoms of ischemic colitis.
  The most common side effects of GaviLyte - H and bisacodyl delayed-release tablet, USP include:
- discomfort
- bloating
- stomach (abdominal) cramping
- nausea
- vomiting

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of GaviLyte - H and bisacodyl delayed-release tablet, USP. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store GaviLyte - H and bisacodyldelayed-release tablet, USP?

- Store GaviLyte - H and bisacodyl delayed-release tablet, USP at 20-25°C (68-77°F)., Excursions permitted between 15-30°C (59-86°F).
- GaviLyte - H solution that has been mixed with water may be refrigerated. Mixed solution should be taken within 48 hours.

Keep GaviLyte - H and bisacodyldelayed-release tablet, USP and all medicines out of the reach of children.

General information about the safe and effective use of GaviLyte - H and bisacodyldelayed-release tablet, USP.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use GaviLyte - H and bisacodyl delayed-release tablet, USP for a condition for which it was not prescribed. Do not give GaviLyte - H and bisacodyl delayed-release tablet, USP to other people, even if they are going to have the same procedure you are. It may harm them.

This Medication Guide summarizes the most important information about GaviLyte - H and bisacodyl delayed-release tablet, USP. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

What are the ingredients in GaviLyte - H and bisacodyldelayed-release tablet, USP?

Active ingredients bisacodyl tablet: bisacodyl.

Inactive ingredients bisacodyl tablet: lactose (anhydrous) NF, microcrystalline cellulose NF, croscarmellose sodium NF, magnesium stearate NF, methacrylic acid copolymer, talc, titanium dioxide, triethyl citrate, D&C red # 27/phloxine aluminum lake, colloidal anhydrous silica, sodium bicarbonate, sodium lauryl sulfate, FD&C blue # 2/indigo carmine aluminum lake and FD&C yellow # 6/sunset yellow FCF aluminum lake.

Active ingredients GaviLyte - H: polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride.

Inactive ingredients GaviLyte - H: cherry, lemon, and orange flavor packs.

Manufactured by:

Novel Laboratories, Inc.
Somerset, NJ 08873

Manufactured for:

GAVIS Pharmaceuticals LLC

Somerset, NJ 08873

This Medication Guide has been approved by the U.S. Food and Drug Administration.

PI0701700201
Iss. 12/2014

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Carton

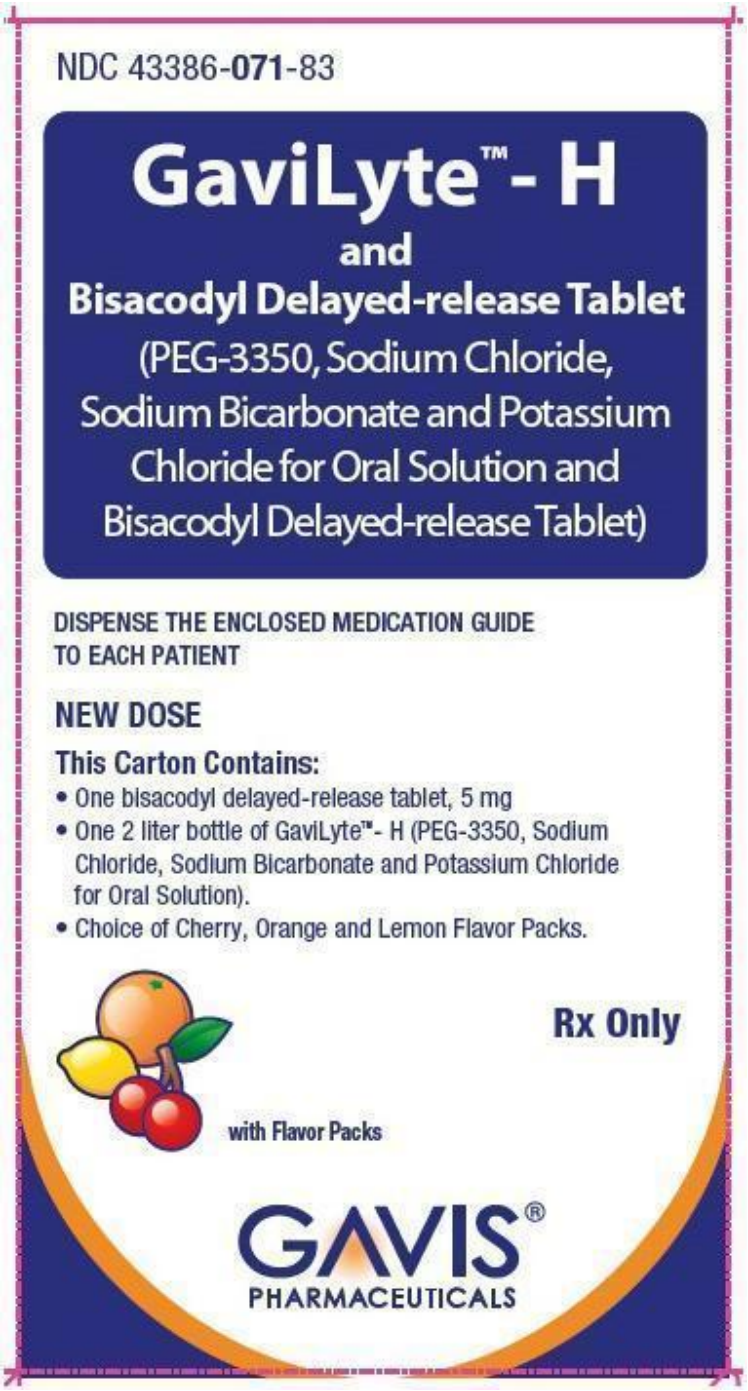
With Flavor Packs

Rx Only

New Dose

GaviLyte - H and bisacodyl delayed-release tablet, USP

Front Panel



Back Panel

NDC 43386-**071**-83

GaviLyte™ - H

and

Bisacodyl Delayed-release Tablet

(PEG-3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution and Bisacodyl Delayed-release Tablet)

DISPENSE THE ENCLOSED MEDICATION GUIDE TO EACH PATIENT

Rx Only

Manufactured by
Novel Laboratories, Inc.
Somerset, NJ 08873

Manufactured for
GAVIS Pharmaceuticals LLC
Somerset, NJ 08873
CA0718300201
Iss. 11/2014

N 3 43386-071-83 8

LOT:

EXP:

Side Panel

PATIENT DIRECTIONS

No solid food or milk (clear liquids only) should be taken on the day of the prep. No antacids should be taken within one hour of taking the bisacodyl delayed-release tablet. Your physician will tell you when it's time to begin.

Step 1 **TAKE TABLET**

Swallow bisacodyl delayed-release tablet with water. Do not chew or crush.

Step 2 **MIX SOLUTION**

Tear open one Flavor Pack of choice and pour into GaviLyte™- H bottle. Discard unused packs. Solution can be used with or without the Flavor Packs. **Add drinking water to top line on bottle.** Cap bottle and shake to dissolve. The solution should be used within 48 hours of preparation. The solution may be refrigerated.

Step 3 **WAIT FOR A BOWEL MOVEMENT**

After a bowel movement occurs (usually in 1-6 hours), begin to drink the solution. **Begin drinking the solution after 6 hours even if a bowel movement has not occurred by then.**

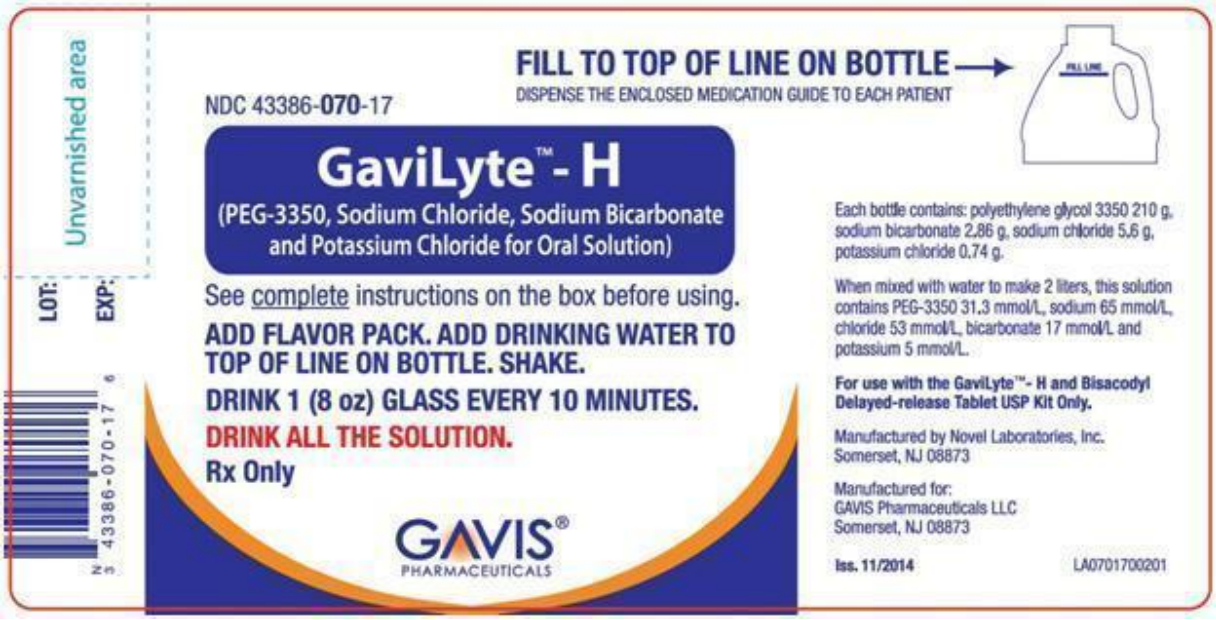
Step 4 **DRINK ALL THE SOLUTION**

Drink 1 (8oz) glass every 10 minutes. A watery bowel movement should begin in approximately 1 hour. **Be sure to drink ALL of the solution.** You will continue to have loose bowel movements for about 1 to 2 hours after finishing.

YOU MUST COMPLETE ALL STEPS.

2 Liter Bottle Label

GaviLyte - H and bisacodyl delayed-release tablet, USP



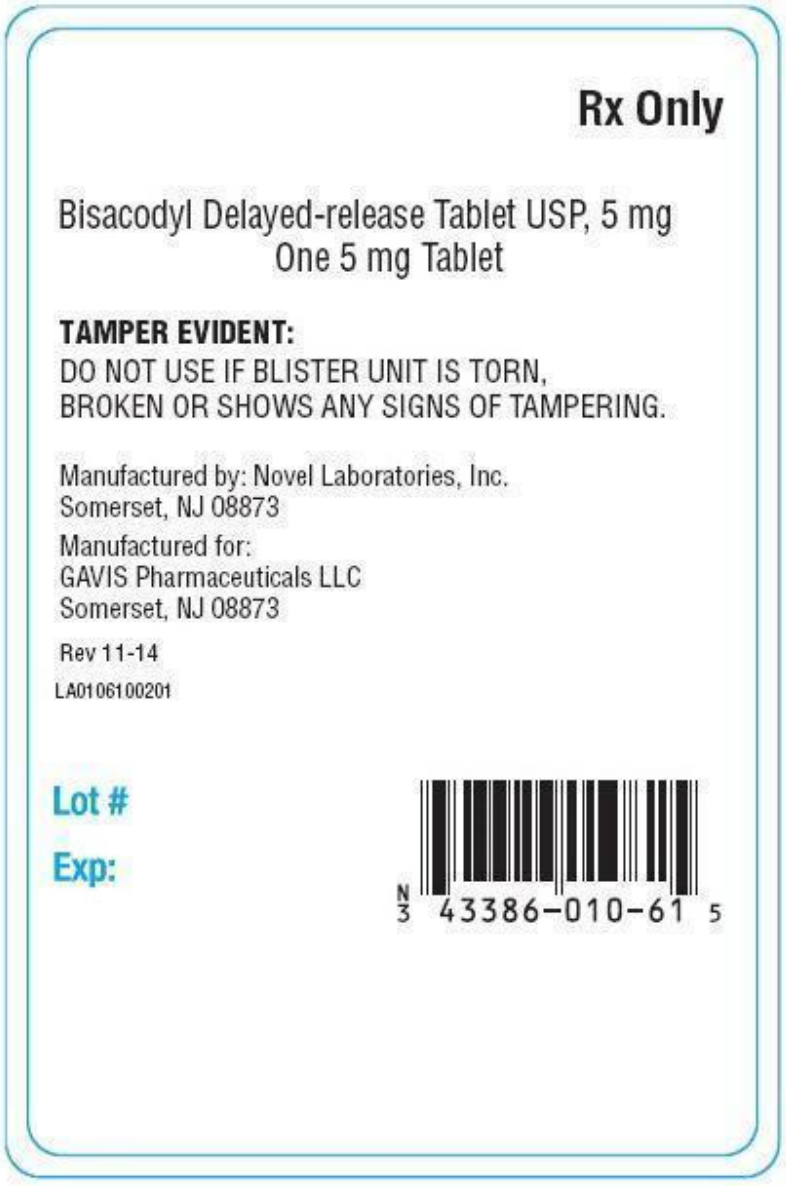
Blister

GaviLyte - H and bisacodyl delayed-release tablet, USP

Front


NEW DOSE
Rx Only
NDC 43386-010-61
Bisacodyl
Delayed-release
Tablet USP, 5 mg
Step 1
One 5 mg
Tablet
TAKE TABLET WITH WATER
Do not chew or crush.
(Your physician will tell you
when to begin)
For use with the GaviLyte™ -H
and Bisacodyl Delayed-release
Tablet, USP Kit Only
Directions to remove the tablet:
Use scissors to cut open blister or peel
back paper and push tablet through.
See directions on GaviLyte™ -H box
before taking

Back



Cherry - Flavor Pack

GaviLyte - H and bisacodyl delayed-release tablet, USP

ATTENTION PHARMACIST:
Dispense all attached flavor packs to the patient.

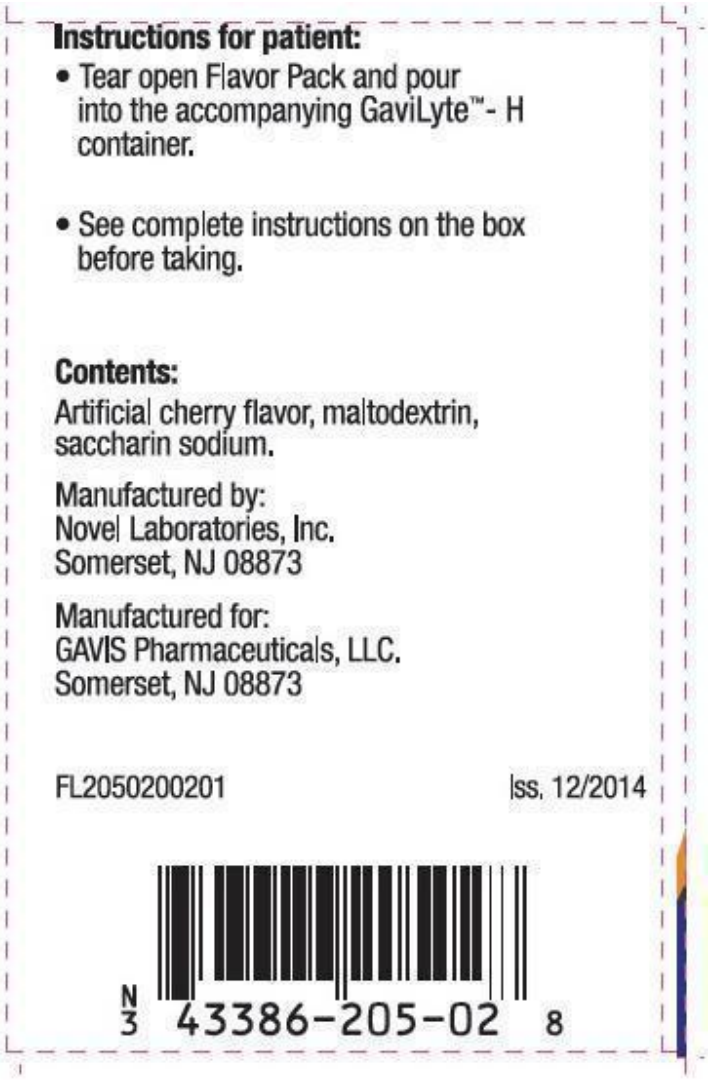
Cherry

Flavor Pack

FOR USE ONLY IN COMBINATION WITH THE ACCOMPANYING CONTAINER.

Net Wt 2g

GAVIS®
PHARMACEUTICALS



Lemon - Flavor Pack

GaviLyte - H and bisacodyl delayed-release tablet, USP

ATTENTION PHARMACIST:
Dispense all attached flavor packs to the patient.

Lemon

Flavor Pack

FOR USE ONLY IN COMBINATION WITH THE ACCOMPANYING CONTAINER.

Net Wt 2g

GAVIS®
PHARMACEUTICALS

Instructions for patient:

- Tear open Flavor Pack and pour into the accompanying GaviLyte™- H container.
- See complete instructions on the box before taking.

Contents:

Natural lemon flavor, maltodextrin, saccharin sodium.

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

Manufactured for:
GAVIS Pharmaceuticals, LLC.
Somerset, NJ 08873

FL2050200201 Iss. 12/2014

Orange - Flavor Pack

GaviLyte - H and bisacodyl delayed-release tablet, USP

ATTENTION PHARMACIST:
Dispense all attached flavor packs to the patient.

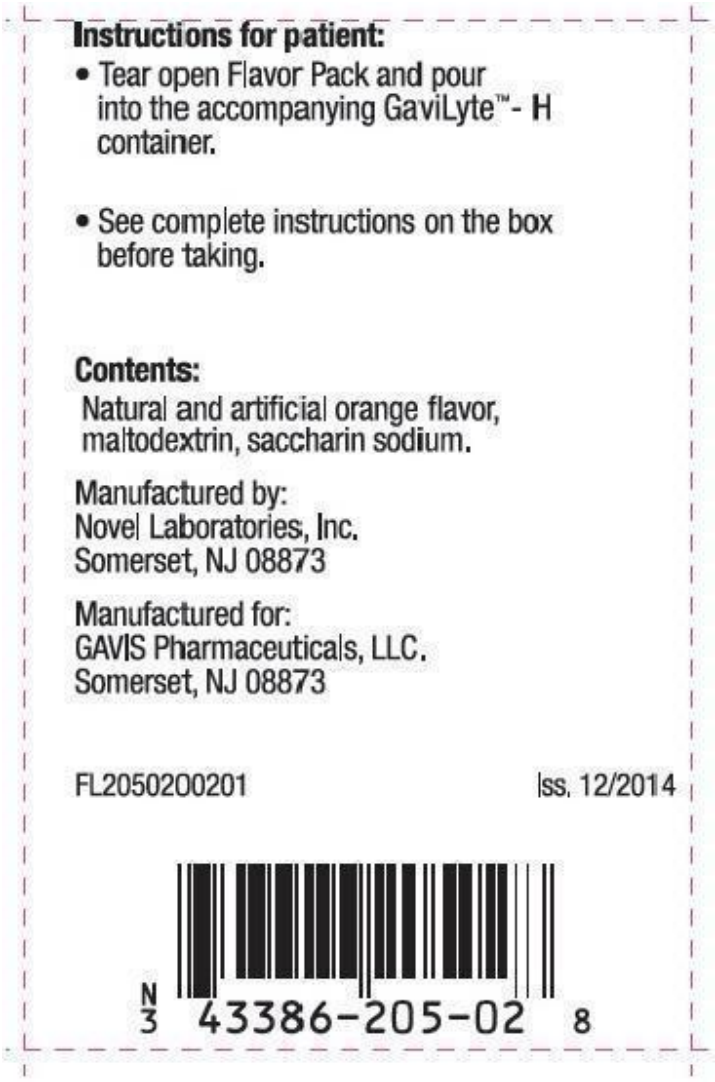
Orange

Flavor Pack

FOR USE ONLY IN COMBINATION WITH THE ACCOMPANYING CONTAINER.

Net Wt 2g

GAVIS®
PHARMACEUTICALS



GAVILYTE-H AND BISACODYL

polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride and bisacodyl delayed-release tablet kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43386-071

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43386-071-83	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	04/21/2015	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	1
Part 2	1 BOTTLE	2 L

Part 1 of 2

BISACODYL

bisacodyl tablet, delayed release

Product Information	
Item Code (Source)	NDC:43386-010
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics			
Color	pink	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	N1
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43386-010-61	1 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202217		

Part 2 of 2

GAVILYTE H

polyethylene glycol-3350, sodium chloride, sodium bicarbonate and potassium chloride powder, for solution

Product Information

Item Code (Source)	NDC:43386-070
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	210 g in 2 L
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	5.6 g in 2 L
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM BICARBONATE	2.86 g in 2 L
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	0.74 g in 2 L

Inactive Ingredients

Ingredient Name	Strength
CHERRY (UNII: BUC5I9595W)	
ORANGE (UNII: 5EVU04N5QU)	
LEMON (UNII: 24RS0A988O)	

Product Characteristics

Color		**Score**	no score
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43386-070-17	2 L in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202217		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202217	04/21/2015	

Labeler - Lupin Pharmaceuticals, Inc. (089153071)

Registrant - Novel Laboratories, Inc. (793518643)

Establishment

Name	Address	ID/FEI	Business Operations
Novel Laboratories, Inc.		793518643	analysis(43386-071) , manufacture(43386-071)

Revised: 1/2025 Lupin Pharmaceuticals, Inc.