



GaviLyte™ – N with Flavor Pack

(PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) with flavor pack.

GAVIS Pharmaceuticals, LLC.

Rx Only

DESCRIPTION

GaviLyte – N is a white powder for reconstitution containing 420 g polyethylene glycol 3350, 5.72 g sodium bicarbonate, 11.2 g sodium chloride, 1.48 g potassium chloride and one 2 g flavor pack (optional). When dissolved in water to a volume of 4 liters, GaviLyte – N (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution) is an isosmotic solution, for oral administration, having a pleasant mineral water taste. GaviLyte – N is administered orally or via nasogastric tube as a gastrointestinal lavage. GaviLyte – N with Flavor Pack is available with optional flavor pack. This preparation can be used without the addition of a GaviLyte – N Flavor Pack.

CLINICAL PHARMACOLOGY

GaviLyte – N induces a diarrhea which rapidly cleanses the bowel, usually within four hours. The osmotic activity of polyethylene glycol 3350 and the electrolyte concentration result in virtually no net absorption or excretion of ions or water. Accordingly, large volumes may be administered without significant changes in fluid or electrolyte balance.

INDICATION AND USAGE

GaviLyte – N is indicated for bowel cleansing prior to colonoscopy.

CONTRAINDICATIONS

GaviLyte – N is contraindicated in patients known to be hypersensitive to any of the components. GaviLyte – N is contraindicated in patients with ileus, gastrointestinal obstruction, gastric retention, bowel perforation, toxic colitis or toxic megacolon.

WARNINGS

GaviLyte – N Flavor Pack is for use only in combination with the contents of the accompanying 4 liter container. No additional ingredients, e.g. flavorings, should be added to

the solution. GaviLyte – N should be used with caution in patients with severe ulcerative colitis. Use of GaviLyte – N in children younger than 2 years of age should be carefully monitored for occurrence of possible hypoglycemia, as this solution has no caloric substrate. Dehydration has been reported in 1 child and hypokalemia has been reported in 3 children.

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 – N, especially if it is administered via nasogastric tube. If a patient experiences severe bloating, distention or abdominal pain, administration should be slowed or temporarily discontinued until the symptoms abate. If gastrointestinal obstruction or perforation is suspected, appropriate studies should be performed to rule out these conditions before administration of GaviLyte – N.

Information for Patients

GaviLyte – N produces a watery stool which cleanses the bowel before examination. Prepare the solution according to the instructions on the bottle. It is more palatable if chilled. For best results, no solid food should be consumed during the 3 to 4 hour period before drinking the solution, but in no case should solid foods be eaten within 2 hours of taking GaviLyte – N.

Adults drink 240 mL (8oz.) every 10 minutes. Continue drinking until the watery stool is clear and free of solid matter. This usually requires at least 3 liters. Any unused portion should be discarded. Pediatric patients (aged 6 months or greater) drink 25 mL/kg/hour. Continue drinking until the watery stool is clear and free of solid matter. Any unused portion should be discarded. Rapid drinking of each portion is better than drinking small amounts continuously. The first bowel movement should occur approximately one hour after the start of GaviLyte – N administration. You may experience some abdominal

bloating and distention before the bowels start to move. If severe discomfort or distention occur, stop drinking temporarily or drink each portion at longer intervals until these symptoms disappear.

Use of GaviLyte – N in children younger than 2 years of age should be carefully monitored for occurrence of possible hypoglycemia, as this solution has no caloric substrate. Dehydration has been reported in 1 child and hypokalemia has been reported in 3 children.

Drug Interactions

Oral medication administered within one hour of the start of administration of GaviLyte – N may be flushed from the gastrointestinal tract and not absorbed.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenic and reproductive studies with animals have not been performed.

Pregnancy

Category C. Animal reproduction studies have not been conducted with GaviLyte – N. It is also not known whether GaviLyte – N can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. GaviLyte – N should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness of GaviLyte – N in pediatric patients aged 6 months and older is supported by evidence from adequate and well-controlled clinical trials of GaviLyte – N in adults with additional safety and efficacy data from published studies of similar formulations.

ADVERSE REACTIONS

Nausea, abdominal fullness and bloating are the most common adverse reactions (occurring in up to 50% of patients) to administration of GaviLyte – N. Abdominal cramps, vomiting and anal irritation occur less frequently. These adverse reactions are transient and subside rapidly. Isolated cases of

urticaria, rhinorrhea, dermatitis and (rarely) anaphylactic reaction have been reported which may represent allergic reactions. Published literature contains isolated reports of serious adverse reaction 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.

DOSAGE AND ADMINISTRATION

GaviLyte – N is usually administered orally, but may be given via nasogastric tube to patients who are unwilling or unable to drink the solution. Ideally, the patient should fast for approximately three or four hours prior to GaviLyte – N administration, but in no case should solid food be given for at least two hours before the solution is given.

Oral administration

Adults: At a rate of 240 mL (8oz.) every 10 minutes, until the rectal effluent is clear or 4 liters are consumed. **Pediatric Patients (aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear. Rapid drinking of each portion is preferred to drinking small amounts continuously. **Nasogastric tube administration:** **Adults:** At a rate of 20 to 30 mL per minute (1.2 to 1.8 liters per hour). **Pediatric Patients (aged 6 months or greater):** At a rate of 25 mL/kg/hour, until the rectal effluent is clear.

The first bowel movement should occur approximately one hour after the start of GaviLyte – N administration. Ingestion of 4 liters of GaviLyte – N solution prior to gastrointestinal examination produces satisfactory preparation in over 95% of patients. Various regimens have been used. One method is to schedule patients for examination in midmorning or later, allowing the patients three hours for drinking and an additional one hour period for complete bowel evacuation. Another method is to administer GaviLyte – N on the evening before examination.

Preparation of the solution: GaviLyte – N solution is prepared by filling the container to the 4 liter mark with water and shaking vigorously several times to insure that the ingredients are dissolved. Dissolution is facilitated by using lukewarm water. The solution is more palatable if chilled before administration. However, chilled solution is not recommended for infants. The reconstituted solution should be refrigerated and used within 48 hours. Discard any unused portion.

HOW SUPPLIED

GaviLyte – N with Flavor Pack is supplied in a disposable jug, in powdered form, for oral administration as a solution following reconstitution. Each jug has an attached flavor pack, in powdered form, for the addition of the flavor pack by the pharmacist prior to dispensing.

GaviLyte – N with Flavor Pack: PEG-3350 420g, sodium bicarbonate 5.72g, sodium chloride 11.2g, potassium chloride 1.48g and flavor pack 2g (optional). When made up to 4 liters volume with water, the solution contains PEG-3350 31.3 mmol/L, sodium 65 mmol/L, chloride 53 mmol/L, bicarbonate 17 mmol/L and potassium 5 mmol/L.

STORAGE: Store in sealed container at 25°C. When reconstituted, keep solution refrigerated. Use within 48 hours. Discard unused portion.

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