VARIBAR THIN HONEY (BARIUM SULFATE) ORAL SUSPENSION, 40% w/v

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VARIBAR THIN HONEY safely and effectively. See full prescribing information for VARIBAR THIN HONEY.

VARIBAR THIN HONEY (barium sulfate) oral suspension

Initial U.S. Approval: 2016

INDICATIONS AND USAGE

VARIBAR THIN HONEY is a radiopaque contrast agent used for modification of barium sulfate for swallowed examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients.

DOSE AND ADMINISTRATION

For oral use only.

- For oral use only — administer by syringe, spoon, or cup. The recommended dose is:
  - Adults: 5 mL
  - Pediatric patients: 1 to 3 mL
- During a single modified barium swallow examination, multiple doses may be administered
  - Maximum cumulative dose: 30 mL

DOSE FORMS AND STRENGTHS

Oral suspension: barium sulfate (40% w/v) supplied in a multiple-dose bottle for oral administration (2).

CONTRAINDICATIONS

- Known or suspected perforation of the GI tract (4)
- Known obstruction of the GI tract (4)
- Conditions associated with high risk of GI perforation or aspiration (4)

ADVERSE REACTIONS

Common adverse reactions include nausea, vomiting, diarrhea and abdominal cramping (6).

The use of VARIBAR THIN HONEY is contraindicated in patients with trachea-esophageal fistula (see Contraindications (4)). Administration of VARIBAR THIN HONEY may result in leakage of barium from the GI tract in the presence of conditions such as carcinomas, GI fistula, inflammatory bowel disease, gastric or duodenal ulcer, appendicitis, or diverticulitis, and in patients with a severe stenosis at any level of the GI tract, especially if it is distal to the stomach. The barium leakage has been associated with peritonitis and granuloma formation.

5.3 Delayed Gastrointestinal Transit and Obstruction

Orally administered barium sulfate may accumulate proximal to a constricting lesion of the colon, causing obstruction or impaction with development of baroliths (inspissated barium associated with feces) and may lead to abdominal pain, appendicitis, bowel obstruction, or rarely perforation. Patients with the following conditions are at higher risk for developing obstruction or baroliths: severe stenosis at any level of the GI tract, impaired GI motility, electrolyte imbalance, dehydration, on a low residue diet, taking medications that delay GI motility, constipation, pediatric patients with cystic fibrosis or Hirschsprung disease, and the elderly [see Use in Specific Populations (8.4, 8.5)]. To reduce the risk of delayed GI transit and obstruction, patients should maintain adequate hydration after the barium sulfate procedure.

5.4 Aspiration Pneumonitis

The use of VARIBAR THIN HONEY is contraindicated in patients with trachea-esophageal fistula [see Contraindications (4)]. Oral administration of barium is associated with aspiration pneumonitis, especially in patients with a history of food aspiration or with compromised swallowing mechanism. Vomiting following oral administration of barium sulfate may lead to aspiration pneumonitis.

In patients at risk for aspiration, begin the procedure with a small ingested volume of VARIBAR THIN HONEY. Monitor the patient closely for aspiration, discontinue administration of VARIBAR THIN HONEY if aspiration is suspected, and monitor for development of aspiration pneumonitis.

5.5 Systemic Embolization

Barium sulfate products may occasionally intravasate into the venous drainage of the GI tract and enter the circulation as a “barium embolus” leading to potentially fatal complications which include systemic and pulmonary embolism, disseminated intravascular coagulation, sepsisemia and prolonged severe hypotension. Although this complication is exceedingly uncommon after oral administration of a barium sulfate suspension, monitor patients for potential intravasation when administering barium sulfate.

ADVERSE REACTIONS

The following adverse reactions have been identified from spontaneous reporting or clinical studies of barium sulfate administered orally. Because the reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or to establish a causal relationship to drug exposure:

- Nausea, vomiting, diarrhea and abdominal cramping
- Serious adverse reactions and fatalities include aspiration pneumonitis, barium sulfate impaction, intestinal perforation with consequent peritonitis and granuloma formation, vasovagal and syncopal episodes

USE IN SPECIFIC POPULATIONS

Pregnancy

VARIBAR THIN HONEY is not absorbed systemically following oral administration, and maternal use is not expected to result in fetal exposure to the drug.
8.2 Lactation  
Risk Summary  
VARIBAR THIN HONEY is not absorbed systemically by the mother following oral administration, and breastfeeding is not expected to result in exposure of the infant to the drug.

8.4 Pediatric Use  
The efficacy of VARIBAR THIN HONEY in pediatric patients is based on successful opacification of the pharynx during modified barium swallow examinations [see Clinical Pharmacology (12.1)]. Safety and dosing recommendations in pediatric patients are based on clinical experience.

VARIBAR THIN HONEY is contraindicated in pediatric patients with trachea-esophageal fistula. [see Contraindications (4)]. Pediatric patients with a history of asthma or food allergies may be at increased risk for development of hypersensitivity reactions [see Warnings and Precautions (5.1)]. Monitor patients with cystic fibrosis or Hirschsprung disease for bowel obstruction after use [see Warnings and Precautions (5.3)].

8.5 Geriatric Use  
Clinical studies of VARIBAR THIN HONEY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

11 DESCRIPTION  
VARIBAR THIN HONEY (barium sulfate) is a radiographic contrast agent that is supplied as an off-white to lightly colored suspension (40% w/v) with an apple aroma for oral administration. The active ingredient barium sulfate is designated chemically as BaSO₄ with a molecular weight of 233.4 g/mol, a density of 4.5 g/cm³, and the following chemical structure:

\[
\begin{align*}
\text{Ba}^{2+} & \quad \left[ \quad \text{O} \quad \text{S} \quad \text{O} \quad \right] \\
\text{O} \quad & \quad \text{O} \\
\end{align*}
\]

VARIBAR THIN HONEY has a viscosity of 1500 cPs and contains the following excipients: carboxymethylcelulose sodium, citric acid, glycerin, natural and artificial apple flavor, polysorbate 80, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, starch modified (from corn), xanthan gum, and xylitol.

12 CLINICAL PHARMACOLOGY  
12.1 Mechanism of Action  
Due to its high atomic number, barium (the active ingredient in VARIBAR THIN HONEY) is opaque to x-rays and therefore acts as a positive contrast agent for radiographic studies.

12.2 Pharmacodynamics  
Barium sulfate is biologically inert and has no known pharmacological effects.

12.3 Pharmacokinetics  
Under physiological conditions, barium sulfate passes through the gastrointestinal tract in an unchanged form and is absorbed only in small, pharmacologically insignificant amounts.

13 NONCLINICAL TOXICOLOGY  
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility  
No animal studies have been performed to evaluate the carcinogenic potential of barium sulfate or potential effects on fertility.

16 HOW SUPPLIED/STORAGE AND HANDLING  
16.1 How Supplied  
VARIBAR THIN HONEY is supplied as a suspension in a multiple-dose polyethylene bottle containing 250 mL of barium sulfate (40 % w/v).

Provided as: 12 x 250 mL bottles (NDC 32909-121-07)

16.2 Storage and Handling  
Store at USP controlled room temperature 20 to 25°C (68 to 77° F). Protect from freezing. Once opened, VARIBAR THIN HONEY may be used for up to 21 days when stored at USP controlled room temperature, 20 to 25°C (68 to 77° F).

17 PATIENT COUNSELING INFORMATION  
After administration, advise patients to:  
- Maintain adequate hydration [see Dosage and Administration (2.2) and Warnings and Precautions (5.3)].
- Seek medical attention for worsening of constipation or slow gastrointestinal passage [see Warnings and Precautions (5.3)].
- Seek medical attention for any delayed onset of hypersensitivity: rash, urticaria, or respiratory difficulty [see Warnings and Precautions (5.1)].

VARIBAR is a registered trademark of E-Z-EM, Inc.  
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For  
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