

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

VARIBAR NECTAR (barium sulfate) oral suspension

Initial U.S. Approval: 2016

-----INDICATIONS AND USAGE-----

VARIBAR NECTAR is a radiographic contrast agent indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients. (1)

-----DOSAGE AND ADMINISTRATION-----

- For oral use only – administered by syringe, spoon, or cup. The recommended dose is:
- Adults: 5 mL
- Pediatric patients 6 months and older: 1-3 mL
- Pediatric patients younger than 6 months of age: 0.5-1 mL
- Maximum cumulative dose: 30 mL
- During a single modified barium swallow examination, multiple doses of VARIBAR NECTAR may be administered. (2)

-----DOSAGE FORMS AND STRENGTHS-----

- Oral suspension –40% (w/v) in a 240 mL multiple-dose HDPE plastic bottle for oral administration (3)

-----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 (4)
- Patients with tracheo-esophageal fistula (4)
- Known severe hypersensitivity to barium sulfate or any of the excipients of VARIBAR NECTAR (4)

-----WARNINGS AND PRECAUTIONS -----

- Hypersensitivity reactions: Emergency equipment and trained personnel should be immediately available (5.1)
- Intra-abdominal barium leakage: May occur in conditions such as GI fistula, ulcer, inflammatory bowel disease, appendicitis or diverticulitis, severe stenosis or obstructing lesions of the GI tract (5.2)
- Delayed GI transit and obstruction: Patients should maintain adequate hydration in days following a barium sulfate procedure to avoid obstruction or impaction (5.3)
- Aspiration pneumonitis: Aspiration may occur during the modified barium swallow examination. Monitor the patient for aspiration (5.4)

-----ADVERSE REACTIONS -----

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

To report SUSPECTED ADVERSE REACTIONS, contact Bracco Diagnostics Inc at 1-800-257-5181 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

See 17 for PATIENT COUNSELING INFORMATION

Revised: 7/2017

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VARIBAR NECTAR is indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

- The recommended dose of VARIBAR NECTAR administered orally by syringe, spoon, or cup:
 - Adults 5 mL
 - Pediatric patients 6 months and older 1-3 mL
 - Pediatric patients younger than 6 months of age 0.5-1 mL(This amount may be administered by an oral syringe or, alternatively, an infant bottle)
- During a single modified barium swallow examination, multiple doses of VARIBAR NECTAR may be administered as appropriate to assess the patient during multiple swallows and different radiographic views.
- The maximum cumulative dose is 30 mL.
- Once opened, write the discard after date on the immediate container label. Discard any unused product after 21 days.

2.2 Important Administration Instructions

For oral use only.

Encourage patients to hydrate following the barium sulfate procedure.

3 DOSAGE FORMS AND STRENGTHS

Oral suspension: barium sulfate (40% w/v) supplied in a multiple dose HDPE plastic bottle as a suspension for oral administration. Each bottle contains 240 mL of suspension.

4 CONTRAINDICATIONS

VARIBAR NECTAR is contraindicated in patients with:

- known or suspected perforation of the GI tract
- known obstruction of the GI tract
- high risk of GI perforation such as those with a recent prior GI perforation, acute GI hemorrhage or ischemia, toxic megacolon, severe ileus, post GI surgery or biopsy, acute GI injury or burn, or recent radiotherapy to the pelvis
- high risk for aspiration such as those with known or suspected tracheo-esophageal fistula or obtundation
- known severe hypersensitivity to barium sulfate or any of the excipients of VARIBAR NECTAR.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Barium sulfate preparations contain a number of excipients, including natural and artificial flavors and may induce serious hypersensitivity reactions. The manifestations include hypotension, bronchospasm and other respiratory impairments, dermal reactions including rashes, urticaria and itching. A history of bronchial asthma, atopy or a previous reaction to a contrast agent may increase the risk for hypersensitivity reactions. Emergency equipment and trained personnel should be immediately available for treatment of a hypersensitivity reaction.

5.2 Intra-abdominal Barium Leakage

The use of VARIBAR NECTAR is contraindicated in patients at high risk of perforation of the GI tract [*see Contraindications (4)*]. Administration of VARIBAR NECTAR may result in leakage of barium at any level of 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 following a barium sulfate procedure.

5.4 Aspiration Pneumonitis

The use of VARIBAR NECTAR is contraindicated in patients with tracheo-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 NECTAR. Aspiration of small volumes of barium sulfate may occur during the modified barium swallow procedure in some patients. Monitor the patient closely for aspiration, discontinue administration 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 large bowel and enter the circulation as a "barium embolus" leading to potentially fatal complications which include systemic and pulmonary embolism, disseminated intravascular coagulation, septicemia and prolonged severe hypotension. Although this complication is exceedingly uncommon after oral administration of barium sulfate products, monitor patients for potential intravasation when administering barium sulfate.

6 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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

VARIBAR NECTAR is not absorbed systemically following oral administration, and maternal use is not expected to result in fetal exposure to the drug [*see Clinical Pharmacology (12.3)*].

8.2 Lactation

Risk Summary

VARIBAR NECTAR is not absorbed systemically by the mother following oral administration, and breastfeeding is not expected to result in exposure of the infant to VARIBAR NECTAR [see *Clinical Pharmacology* (12.3)].

8.4 Pediatric Use

The efficacy of VARIBAR NECTAR in pediatric patients from birth to less than 17 years of age is based on successful opacification of the oropharynx during modified barium swallow examinations [see *Clinical Pharmacology* (12.1)]. Safety and dosing recommendations in pediatric patients are based on clinical experience [see *Dosage and Administration* (2.1)].

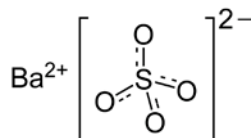
VARIBAR NECTAR is contraindicated in pediatric patients with tracheo-esophageal fistula [see *Contraindications* (4)]. Pediatric patients with a history of asthma or food allergies may be at increased risk for development of hypersensitivity reactions [see *Warnings and Precautions* (5.1)]. Patients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

8.5 Geriatric Use

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



VARIBAR NECTAR has a viscosity of 300 cPs and contains the following excipients: carboxymethylcellulose sodium, citric acid, glycerin, maltodextrin, natural and artificial apple flavor, polysorbate 80, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, xanthan gum, and xylitol.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Due to its high atomic number, barium (the active ingredient in VARIBAR NECTAR) 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 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

How Supplied

VARIBAR NECTAR is supplied in a multiple-dose HDPE bottle containing 240 mL of barium sulfate (40% w/v).

Provided as: 12 x 240 mL bottles (NDC 32909-115-00)

Storage and Handling

Store at USP controlled room temperature 20 to 25°C (68 to 77° F). Protect from freezing.

Once opened, VARIBAR NECTAR 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)*].

Rx only

Manufactured for
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