VARIBAR® (barium sulfate)

VARIBAR® THIN HONEY (barium sulfate) oral suspension
VARIBAR® NECTAR (barium sulfate) oral suspension
VARIBAR® HONEY (barium sulfate) oral suspension
VARIBAR® PUDDING (barium sulfate) oral paste

INDICATIONS
VARIBAR® THIN HONEY (barium sulfate) oral suspension, and VARIBAR® NECTAR (barium sulfate) oral suspension, are radiographic contrast agents indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients.

VARIBAR® HONEY (barium sulfate) oral suspension and VARIBAR® PUDDING (barium sulfate) oral paste are radiographic contrast agents indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients 6 months of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
These products should not be used in patients with known or suspected perforation of the gastrointestinal (GI) tract; known obstruction of the GI tract; high risk of GI perforation such as those with a recent 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 of 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 the product used.

WARNINGS AND PRECAUTIONS

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, and dermal reactions including rashes, urticaria, and itching. A history of bronchial asthma, atopy, food allergies, 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.

Intra-abdominal Barium Leakage
The use of VARIBAR PRODUCTS is contraindicated in patients at high risk of perforation of the GI tract. Administration of VARIBAR PRODUCTS 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.

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. To reduce the risk of delayed GI transit and obstruction, patients should maintain adequate hydration after the barium sulfate procedure. When administering VARIBAR PUDDING, consider the administration of laxatives.

Aspiration Pneumonitis

The use of VARIBAR PRODUCTS is contraindicated in patients with trachea-esophageal fistula. 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 PRODUCTS. Monitor the patient closely for aspiration, discontinue administration of VARIBAR PRODUCTS if aspiration is suspected, and monitor for development of aspiration pneumonitis.

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, septicemia 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 most common adverse reactions are 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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VARIBAR is manufactured by E-Z-EM Canada Inc., for E-Z-EM, Inc., a subsidiary of Bracco Diagnostics Inc., Princeton, NJ 08540.

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

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