

E-Z-PAQUE® (barium sulfate) for oral suspension

INDICATION:

E-Z-PAQUE (barium sulfate) for oral suspension is indicated in adults and pediatrics for use in single contrast radiographic examinations of the esophagus, stomach, duodenum, and small bowel to visualize the gastrointestinal tract (GI).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

E-Z-PAQUE 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 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 prior aspiration, tracheoesophageal fistula, or obtundation
- known severe hypersensitivity to barium sulfate or any of the excipients of E-Z-PAQUE

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Barium sulfate preparations contain excipients, including natural and artificial flavors, and may induce serious hypersensitivity reactions which include hypotension, bronchospasm and other respiratory impairments, and 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.

Intra-abdominal Barium Leakage

Administration of E-Z-PAQUE 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, diverticulitis, and in patients with severe stenosis at any level of the GI tract, especially distal to the stomach. Barium leakage has been associated with peritonitis and granuloma formation.

Delayed Gastrointestinal Transit and Obstruction

Oral barium sulfate may accumulate proximal to a constricting lesion of the colon, causing obstruction or impaction with the development of baroliths (inspissated barium associated with feces) and may cause abdominal pain, appendicitis, bowel obstruction, or rarely perforation. Patients with severe stenosis at any level of the GI tract, impaired GI motility, electrolyte imbalance, dehydration, on a low residue diet, on medications that delay GI motility, constipation, cystic fibrosis, Hirschsprung disease, and the elderly are at higher risk for developing obstruction or baroliths. Maintain adequate hydration during and in the days following a barium sulfate procedure. Consider the administration of laxatives.

Aspiration Pneumonitis

Oral barium is associated with aspiration pneumonitis, especially in patients with a history of food aspiration or with compromised swallowing mechanisms. 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 E-Z-PAQUE. Discontinue administration of E-Z-PAQUE immediately if aspiration is suspected.

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. This complication is exceedingly uncommon after oral administration, monitor patients for potential intravasation when administering barium sulfate.

Risk with Hereditary Fructose Intolerance

E-Z-PAQUE contains sorbitol which may cause severe symptoms in patients with hereditary fructose intolerance including severe symptoms of vomiting, hypoglycemia, jaundice, hemorrhage, hepatomegaly, hyperuricemia, and kidney failure. Before administration of E-Z-PAQUE assess patients for a history of hereditary fructose intolerance and avoid use in these patients.

ADVERSE REACTIONS

The following adverse reactions have been identified from spontaneous reporting or clinical studies of orally administered barium sulfate:

- 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.

Please click [here](#) for full Prescribing Information for E-Z-PAQUE® (barium sulfate) for oral suspension.

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

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

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