READI-CAT® 2 (barium sulfate) oral suspension
READI-CAT® 2 SMOOTHIE (barium sulfate) oral suspension

INDICATION
READI-CAT® 2 and READI-CAT® 2 SMOOTHIE (barium sulfate) oral suspension are indicated for use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
READI-CAT 2 products are contraindicated in patients:
- with known or suspected perforation of the GI tract
- with known obstruction of the GI tract
- at 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 pelvis
- at high risk of aspiration such as those with prior aspiration, tracheo-esophageal fistula, or obtundation
- known severe hypersensitivity to barium sulfate or any of the excipients of READI-CAT 2 or READI-CAT 2 SMOOTHIES

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions Barium sulfate preparations contain a number of excipients, including natural and artificial flavors, and may induce serious hypersensitivity reactions including 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.

Intra-abdominal Barium Leakage The use of READI-CAT 2 products is contraindicated in patients at high risk of perforation of the GI tract. Administration of READI-CAT 2 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 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, and constipation, pediatric patients with cystic fibrosis or Hirschsprung disease, and the elderly are at higher risk for obstruction or baroliths. To reduce the risk of delayed GI transit and obstruction, patients should maintain adequate hydration following a barium sulfate procedure.

Aspiration Pneumonitis The use of READI-CAT 2 products is contraindicated in patients at high risk of aspiration. 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 READI-CAT 2 products. Discontinue administration of READI-CAT 2 products 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. Although this complication is exceedingly uncommon after oral administration of barium sulfate suspension, monitor patients for potential intravasation when administering barium sulfate.

Risk with Hereditary Fructose Intolerance READI-CAT 2 contains sorbitol which may cause severe reactions if ingested by patients with hereditary fructose intolerance, such as vomiting, hypoglycemia, jaundice, hemorrhage, hepatomegaly, hyperuricemia, and kidney failure. Before administration of READI-CAT 2 assess patients for a history of hereditary fructose intolerance and avoid use in these patients.

ADVERSE REACTIONS
Most Common Adverse Events include 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 READI-CAT® 2 products.

READI-CAT 2 is manufactured for Bracco Diagnostics Inc., Princeton, NJ 08540 by E-Z-EM Canada Inc.

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

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