

TAGITOL™ V (barium sulfate) oral suspension

INDICATION

TAGITOL™ V (barium sulfate) oral suspension is indicated for use in adult patients for use in computed tomography (CT) colonography as a fecal tagging agent.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TAGITOL V is contraindicated 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 prior aspiration, tracheo-esophageal fistula, or obtundation
- known hypersensitivity to barium sulfate or any of the excipients of TAGITOL V.

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, 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 TAGITOL V is contraindicated in patients at high risk of perforation of the GI tract and may result in leakage of barium from the GI tract in the presence of conditions that increase the risk of perforation 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 gastrointestinal 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 gastrointestinal 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 barolith. Patients should maintain adequate hydration to reduce the risk of delayed GI transit and obstruction.

Aspiration Pneumonitis The use of TAGITOL V 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.

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, monitor patients for potential intravasation.

ADVERSE REACTIONS

Adverse reactions 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 TAGITOL™ V (barium sulfate) oral suspension.

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

TAGITOL is a trademark of E-Z-EM, Inc.

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