ENTERO VU™ (barium sulfate) oral suspension, 24% w/v

Indication
ENTERO VU™ (barium sulfate) oral suspension is indicated for use in small bowel radiographic examinations to visualize the gastrointestinal (GI) tract in adult patients.

Contraindications
ENTERO VU 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 known or suspected tracheo-esophageal fistula or obtundation, or known severe hypersensitivity to barium sulfate or any of the excipients.

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 ENTERO VU 24% 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 known carcinomas, GI fistula, inflammatory bowel disease, gastric or duodenal ulcer, appendicitis, diverticulitis, and in patients with a severe stenosis at any level of the GI tract, especially if it is distal to the stomach. 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 cause abdominal pain, appendicitis, bowel obstruction, or 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, on medications that delay GI motility, constipation, and the elderly. To reduce the risk of delayed GI transit and obstruction, patients should maintain adequate hydration after the barium sulfate procedure.

Aspiration Pneumonitis
The use of ENTERO VU 24% 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 ENTERO VU 24%. Monitor the patient closely for aspiration, discontinue administration of ENTERO VU 24% 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 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 uncommon after oral administration of a barium sulfate suspension, monitor patients for potential intravasation when administering barium sulfate.

Risk with Hereditary Fructose Intolerance
ENTERO VU 24% contains sorbitol which may cause severe symptoms if ingested by patients with hereditary fructose intolerance. Severe symptoms may include the following: vomiting, hypoglycemia, jaundice, hemorrhage, hepatomegaly, hyperuricemia, and kidney failure. Before administration of ENTERO VU 24% assess patients for a history of hereditary fructose intolerance and avoid use in these patients.

The following adverse reactions have been identified from spontaneous reporting or clinical studies of barium sulfate administered orally and may not reliably estimate the frequency because the reactions are reported voluntarily from a population of uncertain size:

- 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 ENTERO VU™ (barium sulfate) oral suspension, 24% w/v.

ENTERO VU 24% is manufactured for Bracco Diagnostics Inc., Princeton, NJ 08540 by E-Z-EM Canada Inc.

ENTERO VU is a trademark of E-Z-EM, Inc.

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