READI-CAT® 2 (BARIUM SULFATE) ORAL SUSPENSION, 2% w/v

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions: Emergency equipment and trained personnel should be immediately available (5.1)

5.2 Intra-abdominal Barium Leakage

Barium sulfate 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.

5.3 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, and constipation, pediatric patients with cystic fibrosis or Hirschsprung disease, and the elderly [see Use In Specific Populations (8.4, 8.5)]. To reduce the risk of delayed GI transit and obstruction, patients should maintain adequate hydration following a barium sulfate procedure.

5.4 Aspiration Pneumonitis

The use of READI-CAT 2 products is contraindicated in patients at high risk of aspiration [see Contraindications (4)]. 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.

5.5 Systemic Embolization

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.

5.6 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.

6 ADVERSE REACTIONS

6.1 Pregnancy

Risk Summary

READI-CAT 2 products are not absorbed systemically following oral administration, and maternal use is not expected to result in fetal exposure to the drug.

6.2 Lactation

Risk Summary

READI-CAT 2 products are not absorbed systemically by the mother following oral administration, and breastfeeding is not expected to result in exposure of the infant to READI-CAT 2.
8.4 Pediatric Use
The efficacy of READI-CAT 2 in pediatric patients of all age groups is based on successful opacification of the GI tract during radiographic procedures [see Clinical Pharmacology (12.1)].

READI-CAT 2 is contraindicated in pediatric patients with tracheo-esophageal fistula [see Contraindications (4)]. Pediatric patients with a history of asthma or food allergies may be at increased risk for development of hypersensitivity reactions [see Warnings and Precautions (5.1)]. Pediatric patients with cystic fibrosis or Hirschsprung disease should be monitored for bowel obstruction after use [see Warnings and Precautions (5.3)].

8.5 Geriatric Use
Clinical studies of READI-CAT 2 products do not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

11 DESCRIPTION
READI-CAT 2 and READI-CAT 2 SMOOTHIE (barium sulfate) are radiographic contrast agents supplied as a suspension (2% w/v) for oral administration. The active ingredient barium sulfate is designated chemically as BaSO\textsubscript{4} with a molecular weight of 233.4 g/mol, a density of 4.5 g/cm\textsuperscript{3}, and the following chemical structure:

![Chemical Structure of BaSO\textsubscript{4}]

READI-CAT 2 products contain excipients including: benzoic acid, citric acid, potassium sorbate, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol solution, xanthan gum, and purified water.

READI-CAT 2 products also contain natural and artificial flavorings including: banana, blueberry, orange, vanilla, chocolate, and coffee flavors.

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Due to its high atomic number, barium (the active ingredient in READI-CAT 2 products) is opaque to x-rays and therefore acts as a positive contrast agent for radiographic studies.

12.3 Pharmacokinetics
Under physiological conditions, barium sulfate passes through the GI tract in an unchanged form and is absorbed only in pharmacologically insignificant amounts.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
No animal studies have been performed to evaluate the carcinogenic potential of barium sulfate or potential effects on fertility.

16 HOW SUPPLIED/STORAGE AND HANDLING
16.1 How Supplied
READI-CAT 2 and READI-CAT 2 SMOOTHIES (barium sulfate) are supplied as suspensions (2% w/v) in a unit dose in a single-dose HDPE plastic bottle containing 9 grams of barium sulfate in 450 mL.

READI-CAT 2 products are provided in the following flavors as:
READI-CAT 2: (Orange): 12 x 450 mL bottles (NDC 32909-744-03)
READI-CAT 2 SMOOTHIE (Banana): 12 x 450 mL bottles (NDC 32909-742-03)
READI-CAT 2 SMOOTHIE (Berry): 12 x 450 mL bottles (NDC 32909-741-03)
READI-CAT 2 SMOOTHIE (Creamy Vanilla): 12 x 450 mL bottles (NDC 32909-746-03)
READI-CAT 2 SMOOTHIE (Mochaccino): 12 x 450 mL bottles (NDC 32909-747-03)

16.2 Storage and Handling
Store at USP controlled room temperature, 20 to 25°C (68 to 77° F)

17 PATIENT COUNSELING INFORMATION
After administration advise patients to:
• Maintain adequate hydration
• Seek medical attention for worsening of constipation slow gastrointestinal passage
• Seek medical attention for any delayed onset of hypersensitivity: rash, urticaria, or respiratory difficulty.

Manufactured by
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