Bracco Diagnostics

CL10E801

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

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use READI-CAT 2 and READI-CAT 2 SMOOTHIE products safely and effectively. See full prescribing information.

READI-CAT 2 (barium sulfate) oral suspension
READI-CAT 2 SMOOTHIE (barium sulfate) oral suspension
Initial U.S. Approval: 2016

----------RECENT MAJOR CHANGES----------
Warnings and Precautions (5.6) 2/2017

----------INDICATIONS AND USAGE----------
READI-CAT 2 and READI-CAT 2 SMOOTHIE are radiographic contrast agents, indicated for use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients (1)

----------DOSAGE AND ADMINISTRATION-------
For oral use only:
- Adults and pediatric patients 12 years and older: 450 mL to 900 mL (9 g to 18 g of barium sulfate, respectively) (2.1)
- Patients younger than 12 years of age: adjust dose based on relative GI volume (2.1)

-------DOSAGE FORMS AND STRENGTHS-------
- Oral Suspension: 9 grams barium sulfate (2% w/v) supplied in a single-dose HDPE plastic bottle (3)

----------CONTRAINDICATIONS----------
- Known or suspected perforation of the GI tract (4)
- Known obstruction of the GI tract (4)
- Conditions associated with high risk of GI perforation or aspiration (4)
- Known hypersensitivity to barium sulfate or any of the excipients of READI-CAT 2 products (4)

----------WARNINGS AND PRECAUTIONS-------
- Hypersensitivity reactions: Emergency equipment and trained personnel should be immediately available (5.1)
- Intra-abdominal leakage: May occur in conditions such as GI fistula, ulcer, inflammatory bowel disease, appendicitis or diverticulitis, severe stenosis or obstructing lesions of the GI tract (5.2)
- Delayed GI transit and obstruction: Patients should maintain adequate hydration in days following a barium sulfate procedure to avoid obstruction or impaction (5.3)
- Aspiration: Caution is recommended in patients with history of food aspiration and in patients with known swallowing disorders (5.4)

----------ADVERSE REACTIONS----------
Common adverse reactions include nausea, vomiting, diarrhea and abdominal cramping (6)

To report SUSPECTED ADVERSE REACTIONS, contact Bracco Diagnostics Inc at 1-800-257-5181 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 2/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
READI-CAT 2 and READI-CAT 2 SMOOTHIES are indicated for use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients.

2 DOSAGE AND ADMINISTRATION
2.1 Recommended Dosage
Base dosing on individual needs and procedure to be performed
- Adult and pediatric patients 12 years and older: 450 mL to 900 mL (9 g to 18 g of barium sulfate)
- Patients younger than 12 years of age: adjust dose based on relative GI volume

2.2 Administration Instructions
- For oral use only
- Shake bottle vigorously for 30 seconds prior to oral administration
- Administer undiluted prior to scan
- Discard any unused suspension
- Advise patients to hydrate following the barium sulfate procedure

3 DOSAGE FORMS AND STRENGTHS
Oral suspension: 9 grams of barium sulfate supplied as a suspension (2% w/v) in a single-dose HDPE plastic bottle.

4 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

5 WARNINGS AND PRECAUTIONS
5.1 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.

5.2 Intra-abdominal Barium Leakage
The use of READI-CAT 2 products is contraindicated in patients at high risk of perforation of the GI tract *[see Contraindications (4)]*. 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.

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 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.

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
The following adverse reactions have been identified from spontaneous reporting or clinical studies of barium sulfate administered orally. Because the reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or to establish a causal relationship to drug exposure:
- 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

8 USE IN SPECIFIC POPULATIONS
8.1 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.

8.2 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)]*.

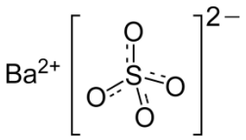
READI-CAT 2 is contraindicated in pediatric patients with tracheo-esophageal fistula *[see Contraindications (4)]*. Pediatric patients with a history of asthma or food allergies may be at increased risk for development of hypersensitivity reactions *[see Warnings and Precautions (5.1)]*. Pediatric patients 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 $BaSO_4$ with a molecular weight of 233.4 g/mol, a density of 4.5 g/cm^3, and the following chemical structure:



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.

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