

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use E-Z-CAT DRY safely and effectively. See full prescribing information for E-Z-CAT DRY.

E-Z-CAT DRY (barium sulfate) for oral suspension
Initial U.S. Approval: 2017

-----INDICATIONS AND USAGE-----

E-Z-CAT DRY is a radiographic contrast agent 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-----

- Recommended reconstituted oral dose for adults and pediatric patients older than 12 years of age is between 450 mL to 900 mL (9 g to 18 g of barium sulfate, respectively) (2.1)
- Pediatric patients younger than 12 years of age adjust reconstituted oral dose based on relative GI volume (2.1)
- Must reconstitute supplied powder with water prior to use. See Full Prescribing Information for reconstitution instructions (2.3)

-----DOSAGE FORMS AND STRENGTHS-----

For oral suspension: 9 grams of barium sulfate (40% w/w) in a single-dose pouch for reconstitution (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 severe hypersensitivity to barium sulfate or any of the excipients of E-Z-CAT DRY (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 and FDA-approved patient labeling.

Revised 01/2017

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

E-Z-CAT DRY is 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

- The recommended dose of reconstituted E-Z-CAT DRY in adults and pediatric patients 12 years and older is between 450 mL to 900 mL given orally (9 to 18 grams of barium sulfate, respectively).
- Patients younger than 12 years of age: adjust dose based on relative GI volume.
- Individualize the dose based on procedure to be performed:
 - Larger volumes of reconstituted E-Z-CAT DRY (up to 900 mL) may be needed for examinations of the distal segments of the GI tract.
 - Administration may begin the night before to allow adequate time for transit of the barium suspension distally.

2.2 Administration Instructions

- E-Z-CAT DRY may be provided to the patient for self-administration.
- Advise patients to carefully read and follow the Patient Instructions for Use and provide any site specific instructions regarding their procedure and when to take the reconstituted E-Z-CAT DRY.
- Administer the product to children less than 12 years of age under the direct supervision of a physician.
- Advise patients to hydrate following barium sulfate procedure.

2.3 Instructions for Reconstitution

- E-Z-CAT DRY should be reconstituted with a 32 oz. mixing container with lid.
- Reconstitute E-Z-CAT DRY prior to administration according to the following instructions:
 - Add 450 mL of water into the mixing container with lid.
 - Pour contents of the foil pouch into the container.
 - Replace the cap tightly on the bottle and invert it to mix the powder with water.
 - Shake vigorously for 20 seconds.
 - Let mixture stand for 5 minutes.
 - Re-shake for 15 seconds prior to use.
 - Discard any unused suspension in normal trash. Do not wash down the drain.

3 DOSAGE FORMS AND STRENGTHS

For oral suspension: 9 grams of barium sulfate supplied as a white to lightly colored powder (40 % w/w) in a single-dose pouch for reconstitution. The suspension is 2% w/v when reconstituted and should be opaque, lightly-colored white and free from particles.

4 CONTRAINDICATIONS

E-Z-CAT DRY 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 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;
- 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 E-Z-CAT DRY.

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 E-Z-CAT DRY is contraindicated in patients at high risk of perforation of the GI tract [*see Contraindications (4)*]. Administration of E-Z-CAT DRY 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, 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 E-Z-CAT DRY 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 E-Z-CAT DRY. Discontinue administration of E-Z-CAT DRY 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

E-Z-CAT Dry 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 E-Z-CAT Dry 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

E-Z-CAT DRY is not absorbed systemically following oral administration and maternal use is not expected to result in fetal exposure to the drug [see *Clinical Pharmacology (12.3)*].

8.2 Lactation

Risk Summary

E-Z-CAT DRY is not absorbed systemically by the mother following oral administration and breastfeeding is not expected to result in exposure of the infant to E-Z-CAT DRY. [see *Clinical Pharmacology (12.3)*].

8.4 Pediatric Use

The efficacy of E-Z-CAT DRY in pediatric patients from birth to less than 17 years of age is based on successful opacification of the GI tract during computed tomography [see *Clinical Pharmacology (12.1)*]. Safety and dosing recommendations in pediatric patients above are based on clinical experience [see *Indications (1), Dosage and Administration (2.1)*].

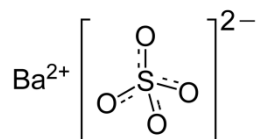
E-Z-CAT DRY is contraindicated in pediatric patients with tracheo-esophageal fistula. [see *Contraindications (4)*]. Pediatric patients with a history of asthma or food allergies may be at increased risk for development of hypersensitivity reactions [see *Warnings and Precautions (5.1)*]. Pediatric patients 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 E-Z-CAT DRY 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

E-Z-CAT DRY (barium sulfate) is a radiographic contrast agent that is supplied as white to lightly colored powder for suspension (40% w/w) with a vanilla aroma for oral administration. It has a molecular weight of 233.4 g/mol and a density of 4.5 g/cm³. The active ingredient barium sulfate is designated chemically as BaSO₄ with the following chemical structure:



E-Z-CAT DRY contains excipients including: artificial candied sugar flavor, carrageenan, citric acid, ethyl vanillin, natural and artificial orange flavor, polysorbate 80, saccharin sodium, simethicone, sodium citrate, sodium carboxymethylcellulose, sorbitol and xanthan gum.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Due to its high atomic number, barium (the active ingredient in E-Z-CAT DRY) 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

E-Z-CAT DRY (barium sulfate) for suspension is supplied as a white to lightly colored powder (40 % w/w) in a single-dose foil pouch containing 9 grams of barium sulfate.

Provided as: Dispenser Box of 50 x 23 gram foil pouches (NDC 32909-727-01)

16.2 Storage and Handling

Store at USP controlled room temperature 20 to 25°C (68 to 77° F).

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Instructions for Use).

After administration, advise patients to:

- Maintain adequate hydration.
- Seek medical attention for worsening for constipation or slow gastrointestinal passage.
- Seek medical attention for any delayed onset of hypersensitivity: rash, urticaria, or respiratory difficulty.

Manufactured by
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Anjou (Quebec) Canada H1J 2Z4

For Bracco Diagnostics Inc.
Monroe Township, NJ 08831

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

Instructions for Use

E-Z-CAT DRY (barium sulfate) for oral suspension

Read these Instructions for Use before you prepare and drink your E-Z-CAT DRY (barium sulfate) oral suspension and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Your healthcare provider will prescribe the dose that is right for you. You can ask your healthcare provider or radiologist if you have questions on how to prepare and take E-Z-CAT DRY.

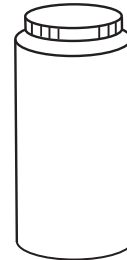
How should I store E-Z-CAT DRY?

Before using E-Z-CAT DRY store at room temperature from 68° F to 77° F (20°C to 25°C).

Keep E-Z-CAT DRY and all medicines out of the reach of children.

Supplies you will need to prepare E-Z-CAT DRY:

- 1 foil pouch of E-Z-CAT DRY
- 1 32 oz mixing container with lid



Important note: These Instructions for Use should only be used with the E-Z-CAT DRY foil pouch and 32 oz mixing container with lid given to you by your healthcare provider or radiologist.

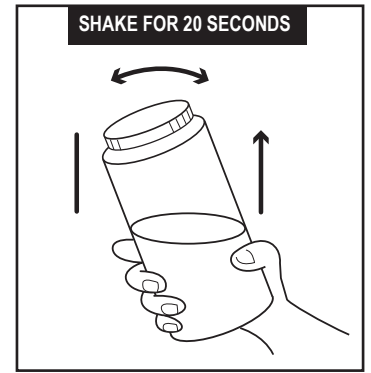
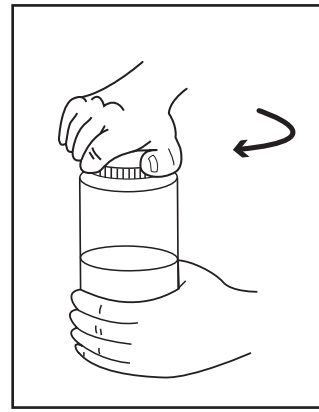
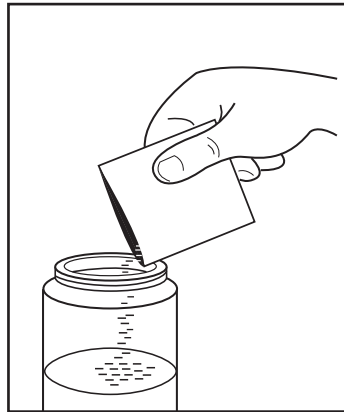
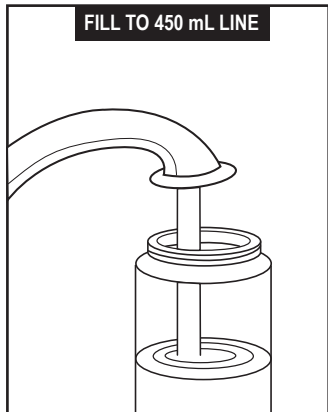
How to prepare your E-Z-CAT DRY:

Step 1. Add room temperature tap water up to the 450 mL line on the mixing container.

Step 2. Open the foil pouch and add the powder to the water in the mixing container.

Step 3. Twist the lid onto the mixing container. Make sure the container is closed tightly.

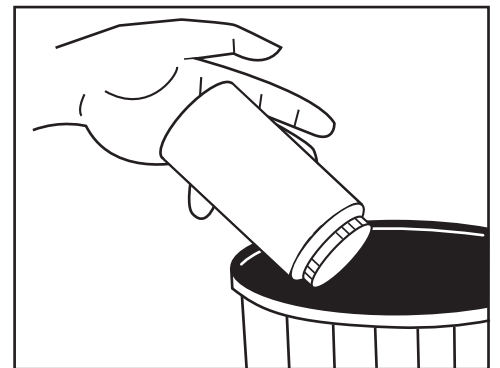
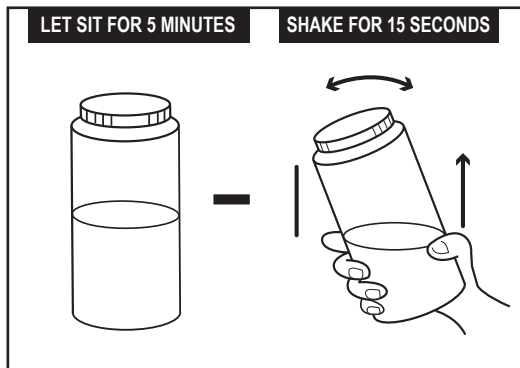
Step 4. Turn the container upside down to mix the powder with water. Shake the container strongly for 20 seconds. The color of the mixture in the container should be white and free of clumps.



Step 5. Put the bottle on a flat surface and **do not** touch it for 5 minutes. Shake the bottle again for 15 seconds.

Step 6. Open the lid and drink the mixture until there is nothing left in the container.

Step 7. Throw away the empty bottle with normal household trash. **Do not** rinse the bottle. **Do not** throw away the mixture by washing down the drain.



What should I do if the E-Z-CAT DRY mixture spills?

If you spill the powder before you mix it or after it is mixed, you can clean it up. E-Z-CAT DRY is not harmful and can be thrown away with normal household trash.

If you spilled any of the powder or mixture, check with your healthcare provider or radiologist to find out if you need to change the date of your procedure appointment.