# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 219840Orig1s000

# LABELING

**HIGHLIGHTS OF PRESCRIBING INFORMATION**
**These highlights do not include all the information needed to use E-Z-DISK safely and effectively. See full prescribing information for E-Z-DISK.**

**E-Z-DISK (barium sulfate) tablets, for oral use**
**Initial U.S. Approval: 2016**

**----------INDICATIONS AND USAGE----------**
E-Z-DISK is a radiographic contrast agent indicated for the evaluation of esophageal patency in adults and pediatric patients aged 12 years and older. (1)

**----------DOSAGE AND ADMINISTRATION----------**
- The recommended dose is one 700 mg tablet orally during imaging.
- Swallow one tablet whole with the aid of one or two swallows of water. Do not cut, crush, or chew the tablet. (2)

**----------DOSAGE FORMS AND STRENGTHS----------**
Tablets: 700 mg of barium sulfate (3)

**----------CONTRAINDICATIONS----------**
- Known severe hypersensitivity to barium sulfate or any of the excipients of E-Z-DISK (4)
- Known or suspected perforation of the gastrointestinal (GI) tract or conditions associated with high risk of GI perforation (4)
- Known obstruction of the GI tract (4)
- Conditions associated with high risk of aspiration (4)

**----------WARNINGS AND PRECAUTIONS----------**
- Hypersensitivity Reactions: Have emergency equipment and trained personnel immediately available during the procedure. (5.1)
- Intra-abdominal Barium Leakage: Barium leakage may occur in conditions such as GI fistula, ulcer, inflammatory bowel disease, appendicitis, diverticulitis, and severe stenosis or obstructing lesions of the GI tract and has been associated with peritonitis and granuloma formation. (5.2)
- Baroliths and Bowel Obstruction: Maintain adequate hydration following a barium sulfate procedure and monitor patients at risk for delayed GI transit for development of signs and symptoms of bowel obstruction. (5.3)
- Aspiration Pneumonitis: Patients with a history of food aspiration or compromised swallowing mechanism may be at high risk. (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: 8/2025**

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**FULL PRESCRIBING INFORMATION: CONTENTS***



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

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**FULL PRESCRIBING INFORMATION**

## 1 INDICATIONS AND USAGE

E-Z-DISK is indicated for the evaluation of esophageal patency in adults and pediatric patients aged 12 years and older.

## 2 DOSAGE AND ADMINISTRATION

The recommended dose of E-Z-DISK in adults and pediatric patients aged 12 years and older is one 700 mg tablet orally during imaging.

Swallow one tablet whole with the aid of one or two swallows of water. Do not cut, crush, or chew the tablet.

Advise patients to hydrate following the E-Z-DISK imaging procedure *[see Warnings and Precautions (5.3)]*.

E-Z-DISK is formulated to disintegrate within the gastrointestinal (GI) tract. In the event of prolonged retention, consider implementing appropriate interventions.

## 3 DOSAGE FORMS AND STRENGTHS

Tablets: 700 mg of barium sulfate as a white to lightly colored, between 11.5 mm and 13.5 mm (0.45 inch and 0.53 inch) in diameter, flat-sided disk with EZEM inscribed on one side and 778 on the other side.

## 4 CONTRAINDICATIONS

E-Z-DISK is contraindicated in patients with:

- Known severe hypersensitivity to barium sulfate or any of the excipients of E-Z-DISK *[see Warnings and Precautions (5.1)]*
- Known, suspected, or high risk of perforation of the GI tract such as patients with a recent GI perforation, acute GI hemorrhage or ischemia, toxic megacolon, severe ileus, recent GI surgery or biopsy, acute GI injury, or recent radiotherapy to the pelvis *[see Warnings and Precautions (5.2)]*
- Known obstruction of the GI tract *[see Warnings and Precautions (5.3)]*
- High risk of aspiration such as patients with known or suspected tracheoesophageal fistula or obtundation *[see Warnings and Precautions (5.4)]*

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Hypersensitivity Reactions

E-Z-DISK may induce serious hypersensitivity reactions with manifestations including hypotension, bronchospasm and other respiratory impairments, and dermal reactions including rashes, urticaria and itching. A history of bronchial asthma, atopy, food allergies, or a reaction to a contrast agent may increase the risk for hypersensitivity reactions. E-Z-DISK is contraindicated in patients with known severe hypersensitivity to barium sulfate or any of the excipients of E-Z-DISK *[see Contraindications (4)]*. Have emergency equipment and trained personnel immediately available during the procedure.

### 5.2 Intra-abdominal Barium Leakage

Barium leakage from the GI tract has been associated with peritonitis and granuloma formation. Barium sulfate

from orally administered E-Z-DISK may leak in the presence of conditions such as carcinomas, GI fistula, inflammatory bowel disease, gastric or duodenal ulcer, appendicitis, or diverticulitis, and in patients with severe stenosis of the GI tract, especially if it is distal to the stomach. E-Z-DISK is contraindicated in patients with known, suspected, or high risk of perforation of the GI tract *[see Contraindications (4)]*.

### 5.3 Baroliths and Bowel Obstruction

Barium sulfate from orally administered E-Z-DISK may accumulate in the GI tract, causing obstruction or impaction with development of baroliths (inspissated barium associated with feces) and may lead to abdominal pain, appendicitis, or perforation. Patients with the following are at higher risk for developing obstruction or baroliths: severe stenosis at any level of the GI tract, impaired GI motility, electrolyte imbalance, dehydration, low residue diet, medications that delay GI motility, constipation, pediatric patients with cystic fibrosis or Hirschsprung disease, and advanced age. E-Z-DISK is contraindicated in patients with known obstruction of the GI tract *[see Contraindications (4)]*. To reduce the risk of delayed GI transit and obstruction, maintain adequate hydration after the E-Z-DISK procedure. Monitor patients at risk for delayed gastrointestinal transit for development of signs and symptoms of bowel obstruction.

### 5.4 Aspiration Pneumonitis

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. E-Z-DISK is contraindicated in patients with high risk of aspiration such as known or suspected tracheoesophageal fistula or obtundation *[see Contraindications (4)]*.

### 5.5 Systemic Embolization

Barium sulfate from orally administered E-Z-DISK may intravasate into the venous drainage of the GI tract 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.

## 6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Hypersensitivity Reactions *[see Warnings and Precautions (5.1)]*
- Intra-abdominal Barium Leakage *[see Warnings and Precautions (5.2)]*
- Baroliths and Bowel Obstruction *[see Warnings and Precautions (5.3)]*
- Aspiration Pneumonitis *[see Warnings and Precautions (5.4)]*

The following adverse reactions associated with the use of E-Z-DISK or other barium sulfate products were identified in postmarketing reports or published clinical studies. Because some of these 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:

*Cardiovascular disorders*: Vasovagal and syncopal episodes
*Gastrointestinal disorders:* Barium sulfate impaction, nausea, vomiting, diarrhea, abdominal cramping
*Respiratory disorders*: Aspiration pneumonitis

Adverse Reactions in Pediatric Patients

No additional safety signals have been reported in pediatric patients aged 12 years and older.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Risk Summary

Barium sulfate is not absorbed systemically following oral administration, and maternal use is not expected to result in fetal exposure to E-Z-DISK *[see Clinical Pharmacology (12.3)]*.

### 8.2 Lactation

Risk Summary

Barium sulfate 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-DISK.

### 8.4 Pediatric Use

The safety and effectiveness of E-Z-DISK for use in radiographic evaluation of esophageal patency have been established in pediatric patients 12 years and older. Use of E-Z-DISK in this age group for this indication is supported by effectiveness established in studies of adults and pediatric safety data from other barium sulfate products *[see Adverse Reactions (6)]*.

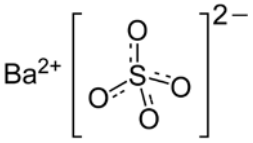
### 8.5 Geriatric Use

Reported clinical experience has not identified differences between elderly and younger patients.

## 11 DESCRIPTION

E-Z-DISK (barium sulfate) tablet is a radiographic contrast agent for oral use.

Barium sulfate is designated chemically as $BaSO_4$ with molecular weight of 233.4 g/mol, density of 4.5 g/cm$^3$, and the following chemical structure:



E-Z-DISK is a white to lightly colored, flat-sided disk, between 11.5 mm and 13.5 mm (0.45 inch and 0.53 inch) in diameter. Each tablet contains 700 mg barium sulfate and the following inactive ingredients: confectioner's sugar, microcrystalline cellulose, corn starch, povidone, croscarmellose sodium, and magnesium stearate.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

E-Z-DISK is formulated to pass through the esophagus into the stomach when the esophageal lumen is greater than 11.5 mm to 13.5 mm (0.45 inch to 0.53 inch) in diameter. Due to its high atomic number, barium is opaque to X-rays and therefore acts as a positive contrast agent for radiographic studies.

### 12.2 Pharmacodynamics

Barium sulfate has no pharmacological effects.

### 12.3 Pharmacokinetics

Orally administered barium sulfate passes through the gastrointestinal tract in an unchanged form and is absorbed only in 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

How Supplied

E-Z-DISK (barium sulfate) tablets, 700 mg, are white to lightly colored, between 11.5 mm and 13.5 mm (0.45 inch and 0.53 inch) in diameter, flat-sided disks with EZEM inscribed on one side and 778 on the other side supplied in a glass bottle containing 100 tablets (NDC 10361-778-31).

Storage and Handling

Store at 20°C to 25°C (68°F to 77° F) [see USP controlled room temperature]. Store in original container and protect from moisture.

## 17 PATIENT COUNSELING INFORMATION

Administration Instructions

Instruct patients to swallow E-Z-DISK as a whole tablet with the aid of one or two swallows of water (do not cut, crush, or chew) *[see Dosage and Administration (2.2)]*.

Hypersensitivity Reactions

Advise patients to seek medical attention for any delayed onset of hypersensitivity such as rash, urticaria, or respiratory difficulty *[see Warnings and Precautions (5.1)]*.

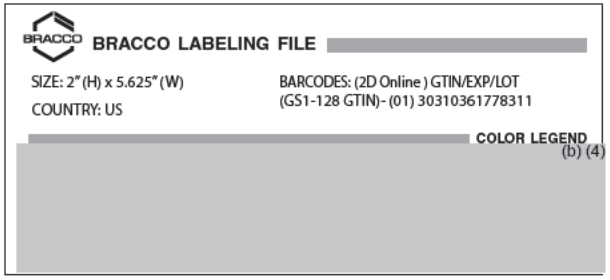
Baroliths and Bowel Obstruction

Advise patients to drink a sufficient amount of water to maintain adequate hydration following the E-Z-DISK procedure and to seek medical attention for signs and symptoms of bowel obstruction *[see Warnings and Precautions (5.3)]*.

Manufactured by:
Confab Laboratories Inc.
Saint Hubert (Quebec) Canada J3Y 3X3

Manufactured for:
E-Z-EM, Inc.
a subsidiary of Bracco Diagnostics Inc.
Princeton, NJ 08540


GTIN (01) 30310361778311
EXP. (17) YYYY-MMM-DD
LOT (10) XXXXXXX
Non-varnish area
Bracco Diagnostics
100 Tablets
NDC 10361-778-31
E-Z-DISK™
(BARIUM SULFATE) Tablets
700 mg
For Oral Use Only
℞ Only
Manufactured for
Bracco Diagnostics Inc.
Princeton, NJ 08540
by Confab Laboratories Inc.
Saint Hubert (Québec), Canada J3Y 3X3
(01)30310361778311
Recommended Dosage: see Prescribing Information
Each tablet contains 700 mg barium sulfate and the following inactive ingredients: confectioner's sugar, microcrystalline cellulose, corn starch, povidone, croscarmellose sodium, magnesium stearate.
Indicated for the evaluation of esophageal patency in adults and pediatric patients aged 12 years and older.
Store at room temperature 20°C to 25°C (68°F to 77°F) see USP controlled room temperature . Store in original container and protect from moisture.
DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN OR MISSING
rev. XX/XX 300054-0X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