E-Z-HD™ (BARIUM SULFATE) FOR ORAL SUSPENSION, 98% w/w

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

E-Z-HD (barium sulfate) for oral suspension

Recent U.S. Approval: 2016

DOSE FORMS AND STRENGTHS
- 334 grams of barium sulfate (98% w/w) in a single-dose bottle for reconstitution

CONTRAINDICATIONS
- E-Z-HD is contraindicated in patients:
  - Known or suspected perforation of the GI tract
  - 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 the pelvis
  - High risk of aspiration such as those with prior aspiration, tracheo-esophageal fistula, or obtundation
  - With known severe hypersensitivity to barium sulfate or any of the excipients of E-Z-HD

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, 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.

Aspiration Pneumonitis
E-Z-HD is contraindicated in patients with a severe stenosis at any level of the GI tract, especially if it is distal to the stomach. The barium sulfate 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 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)].

Aspiration Pneumonitis
The use of E-Z-HD is contraindicated in patients at high risk of aspiration [see Contraindications (4)]. Administration of E-Z-HD 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 sulfate has been associated with peritonitis and granuloma formation.

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 a barium sulfate suspension, monitor patients for potential intravasation when administering barium sulfate.

Risk with Hereditary Fructose Intolerance
E-Z-HD 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 E-Z-HD assess patients for a history of hereditary fructose intolerance and avoid use in these patients.

DOSAGE FORMS AND STRENGTHS
For oral suspension: 334 grams of barium sulfate (98% w/w) in a single-dose bottle for reconstitution (3)

Full prescribing information for reconstitution instructions (2.2)

Contraindications (4)

E-Z-HD is contraindicated in patients:
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- 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 the pelvis
- At high risk of aspiration such as those with prior aspiration, tracheo-esophageal fistula, or obtundation
- With known severe hypersensitivity to barium sulfate or any of the E-Z-HD excipients

Dosage and Administration

Recommended reconstituted oral dose for adults and pediatric patients 12 years and older is between 65 mL to 135 mL (155 to 321 grams of barium sulfate, respectively). Volumes closer to 65 mL are recommended for the examination of the esophagus, stomach and duodenum to help visualize the gastrointestinal (GI) tract in patients 12 years and older (1)

Dosage and Administration Instructions
- Recommended reconstituted oral dose for adults and pediatric patients 12 years and older is between 65 mL to 135 mL (155 to 321 grams of barium sulfate, respectively). Volumes closer to 65 mL are recommended for the examination of the esophagus, stomach and duodenum to help visualize the gastrointestinal (GI) tract in patients 12 years and older (1)
- Must reconstitute supplied powder with water prior to use. See Full Prescribing Information for reconstitution instructions (2.2)

Drug Interactions
- Medications that delay GI motility, constipation, pediatric patients with cystic fibrosis or Hirschsprung disease, and the elderly
- Oral administration of laxatives.

Warnings and Precautions
- Emergency equipment and trained personnel should be immediately available for treatment of a serious hypersensitivity reaction (5.1).
- Conditions associated to high risk of GI perforation (4)

Contraindications
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  - Known or suspected perforation of the GI tract
  - 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 the pelvis
  - At high risk of aspiration such as those with prior aspiration, tracheo-esophageal fistula, or obtundation
  - With known severe hypersensitivity to barium sulfate or any of the E-Z-HD excipients

Full prescribing information for use in specific populations (8.4, 8.5)

E-Z-HD (barium sulfate) for oral suspension

Full prescribing information for use in specific populations (8.4, 8.5)

Full prescribing information for reconstitution instructions (2.2)
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-HD is 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
E-Z-HD 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-HD.

8.4 Pediatric Use
Double-contrast radiographic examinations of the esophagus, stomach and duodenum may be used in pediatric patients 12 years and older.

E-Z-HD 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-HD did 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-HD barium sulfate is a radiographic contrast agent that is supplied as a fine, white to lightly colored powder for suspension (98 % w/w) for oral administration. The active ingredient barium sulfate is designated chemically as BaSO₄ with a molecular weight of 233.43 g/mol, a density of 4.5 g/cm³, and the following chemical structure:

![Chemical structure of BaSO₄]

E-Z-HD contains excipients including: acacia, artificial cherry flavor, artificial strawberry flavor, carrageenan, citric acid, ethyl maltol, polysorbate 80, saccharin sodium, simethicone, sodium citrate, and sorbitol.

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Due to its high atomic number, barium (the active ingredient in E-Z-HD) 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-HD (barium sulfate) for suspension, is supplied as a fine, white to lightly colored powder (98 % w/w) in a single-dose HDPE plastic bottle containing 334 grams of barium sulfate.

Provided as: 24 bottles per pack (NDC 32909-764-01)

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 or slow gastrointestinal passage
• Seek medical attention for any delayed onset of hypersensitivity: rash, urticaria, or respiratory difficulty

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