VARIBAR PUDDING- barium sulfate paste
E-Z-EM Canada Inc

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VARIBAR PUDDING safely and effectively. See full prescribing information for VARIBAR PUDDING.
VARIBAR PUDDING (barium sulfate) oral paste
Initial U.S. Approval: 2016

INDICATIONS AND USAGE

VARIBAR PUDDING is a radiographic contrast agent indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients 6 months of age and older (1)

DOSAGE AND ADMINISTRATION

- For oral use only – administered by syringe or spoon (2.1)
  - Adults: 5 mL
  - Pediatric patients: 1-3 mL
- Multiple doses may be administered
- Maximum cumulative dose : 30 mL

DOSAGE FORMS AND STRENGTHS

Oral paste: barium sulfate (40% w/v) in a 30 mL or 230 mL multiple dose tube for oral administration (3)

CONTRAINDICATIONS

VARIBAR PUDDING is contraindicated in patients with:

- Known or suspected perforation of the gastrointestinal (GI) tract (4)
- Conditions associated with high risk for GI perforation (4)
- Known obstruction of the GI tract (4)
- Patients with trachea-esophageal fistula (4)
- Known hypersensitivity to barium sulfate or any of the excipients of VARIBAR PUDDING (4)

WARNINGS AND PRECAUTIONS

- Hypersensitivity reactions: Emergency equipment and trained personnel should be immediately available (5.1)
- Intra-abdominal leakage: May occur with conditions which increase the risk for perforation such as – carcinomas, GI fistula, Inflammatory bowel disease, gastric or duodenal ulcer, appendicitis, diverticulitis, or severe stenosis or obstructing lesions of the GI tract (5.2)
- Obstruction: Patients should maintain adequate hydration in days following barium sulfate procedure to avoid obstruction or impaction by baroliths (5.3)
- Aspiration Pneumonitis: Aspiration may occur during the modified barium swallow examination, monitor the patient for aspiration (5.4)

ADVERSE REACTIONS

Common adverse reactions include nausea, vomiting, diarrhea and abdominal cramping (6)
To report SUSPECTED ADVERSE REACTIONS, contact Bracco Diagnostics at 1-800-257-5181 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION.

Revised: 5/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VARIBAR PUDDING is indicated for modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients 6 months of age and older.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

- The recommended oral dose of VARIBAR PUDDING delivered by oral syringe or spoon:
  - Adults 5 mL
  - Pediatric patients 1-3 mL
- During a single modified barium swallow examination, multiple doses of VARIBAR PUDDING may be administered as appropriate, to assess the patient during multiple swallows and different radiographic views.
- The maximum cumulative dose is 30 mL oral.

- Once opened, write the discard after date on the immediate container label. Discard any unused product after 21 days.

2.2 Important Administration Instructions

- Advise patients to hydrate following the barium sulfate procedure.
- Advise patient at risk for constipation or delayed gastrointestinal transit to monitor for worsening of their condition after administration of barium sulfate and seek medical attention if worsening and advise using laxatives to enhance gastrointestinal transit.

3 DOSAGE FORMS AND STRENGTHS

Oral paste: barium sulfate (40% w/v) supplied in a multiple-dose white polyethylene tube as a ready-to-use paste for oral administration. Each tube contains either 30 mL or 230 mL of paste.

4 CONTRAINDICATIONS

VARIBAR PUDDING 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 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 for aspiration such as those with known or suspected tracheo-esophageal fistula or obtundation;
- known hypersensitivity to barium sulfate or any of the excipients of VARIBAR PUDDING.

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, and dermal reactions including rashes, urticaria, and itching. A history of bronchial asthma, atopy, food allergies, 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

Administration of VARIBAR PUDDING may result in leakage of barium from the GI tract in the presence of conditions and ailments that increase the risk of perforation such as known 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 gastrointestinal tract, especially if it is distal to the stomach. The barium leakage has been associated with peritonitis and granuloma formation. The use of VARIBAR

PUDDING is contraindicated in patients at high risk of perforation of the GI tract *[see Contraindications (4)]*.

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, with impaired gastrointestinal 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 after the barium sulfate procedure and consider the administration of laxatives.

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. In patients at risk for aspiration, begin the procedure with a small ingested volume of VARIBAR PUDDING. The use of VARIBAR PUDDING is contraindicated in patients with trachea-esophageal fistula *[see Contraindications (4)]*. Monitor the patient closely for aspiration, discontinue administration of VARIBAR PUDDING if aspiration is suspected, and monitor for development of aspiration pneumonitis.

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

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

VARIBAR PUDDING 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

VARIBAR PUDDING is not absorbed systemically by the mother following oral administration and breastfeeding is not expected to result in exposure of the infant to the drug. *[see Clinical Pharmacology (12.3)]*

8.4 Pediatric Use

The efficacy of VARIBAR PUDDING in pediatric patients above 6 months of age is based on successful opacification of the pharynx during modified barium swallow examinations *[see Clinical Pharmacology (12.1)]*. Safety and dosing recommendations in pediatric patients above 6 months of age are based on clinical experience *[see Indications (1), Dosage and Administration (2.1)]*.

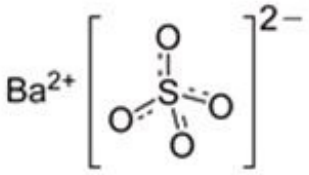
VARIBAR PUDDING is contraindicated in pediatric patients with tracheo-esophageal fistula. [see Contraindications (4)]. Pediatric patients with a history of asthma or food allergies may be at increased risk for development of hypersensitivity reactions *[see Warnings and Precautions (5.1)]*. Pediatric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

VARIBAR PUDDING (barium sulfate) is a radiographic contrast agent that is supplied as a 40 % w/v ready to use paste with a vanilla aroma for oral administration. The active ingredient barium sulfate is designated chemically as $BaSO_4$ with a molecular weight of 233.4 g/mol and the following chemical structure:



VARIBAR PUDDING has a viscosity of 5000 cPs and contains the following excipients: artificial vanilla flavor, carboxymethylcellulose sodium, citric acid, ethyl vanillin, glycerin, maltodextrin, polysorbate 80, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, xanthan gum, and xylitol.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Due to its high atomic number, barium (the active ingredient in VARIBAR PUDDING) is opaque to x-rays and therefore acts as a positive contrast agent for radiographic studies.

12.2 Pharmacodynamics

Barium sulfate is biologically inert and has no known pharmacological effects.

12.3 Pharmacokinetics

Under physiological conditions, barium sulfate passes through the gastrointestinal tract in an unchanged form and is absorbed only in small, 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

VARIBAR PUDDING is supplied as a paste in a multiple-dose polyethylene tube containing either 30 mL or 230 mL of barium sulfate (40 % w/v).

Provided as: 24 X 30 mL tubes (NDC 32909-125-54); 12 X 230 mL tubes (NDC 32909-125-22)

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

Once opened, VARIBAR PUDDING may be used for up to 21 days when stored at USP

controlled room temperature, 20°C to 25°C (68°F 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.

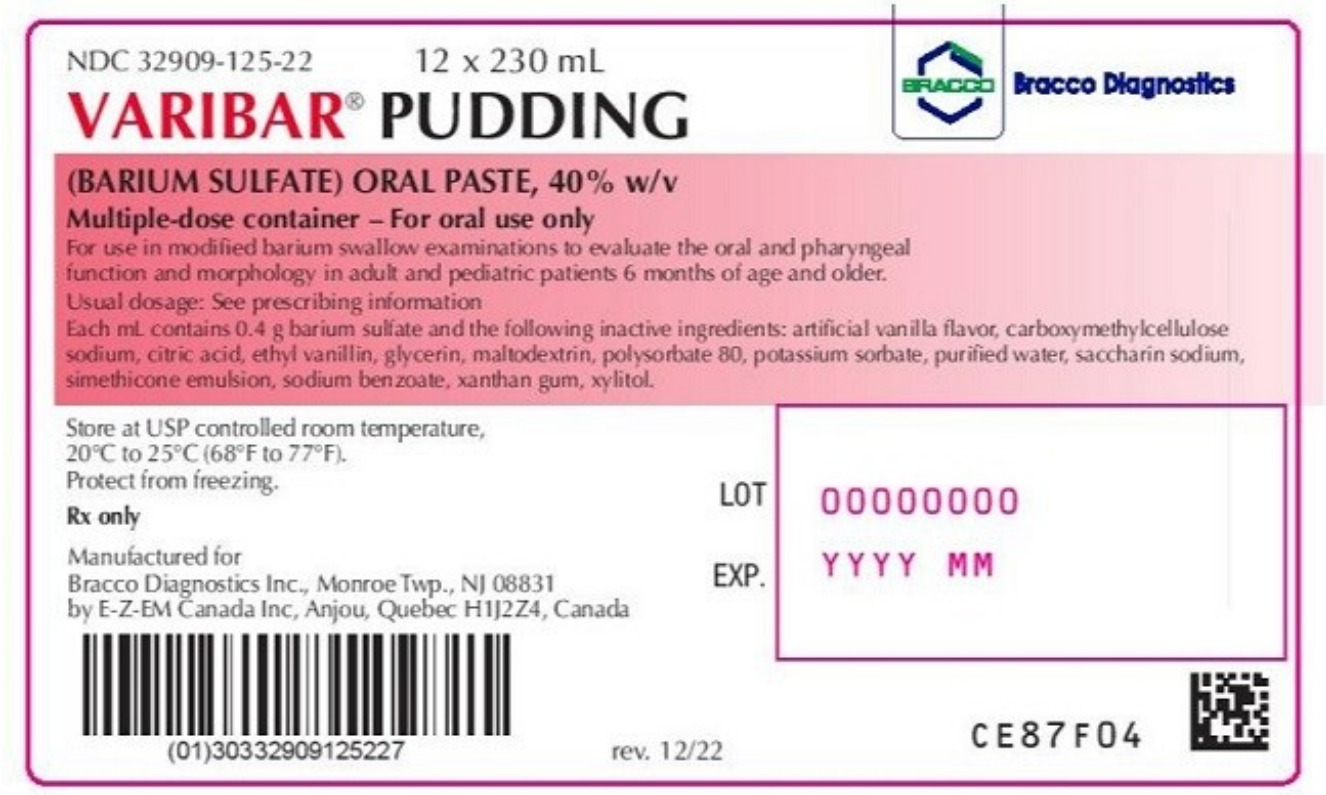
Rx only

Manufactured for
Bracco Diagnostics Inc.
Monroe Township, NJ 08831
by EZEM Canada Inc
Anjou (Quebec) Canada H1J 2Z4

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

Revised: August 2024
CL87D-04

230 mL Varibar Pudding Label



230 mL Varibar Pudding Tube

EXP YYYY MM LOT 00000000

Multiple-dose container –
For oral use only

See prescribing information for complete dosage and administration information.

Each mL contains 0.4 g barium sulfate and the following inactive ingredients: artificial vanilla flavor, carboxymethylcellulose sodium, citric acid, ethyl vanillin, glycerin, maltodextrin, polysorbate 80, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, xanthan gum, xylitol.

For use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients 6 months of age and older.

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

Once opened, may be used for up to 21 days when stored at USP controlled room temperature, 20°C to 25°C (68°F to 77°F).

DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN OR MISSING

Record discard date in the space provided below.

Discard After ____/____/____

(01)10332909125223

rev. 12/2022

CT88005

BACK

Bracco Diagnostics

230 mL NDC 32909-125-22

VARIBAR®
PUDDING

(BARIUM SULFATE)
ORAL PASTE,
40% w/v

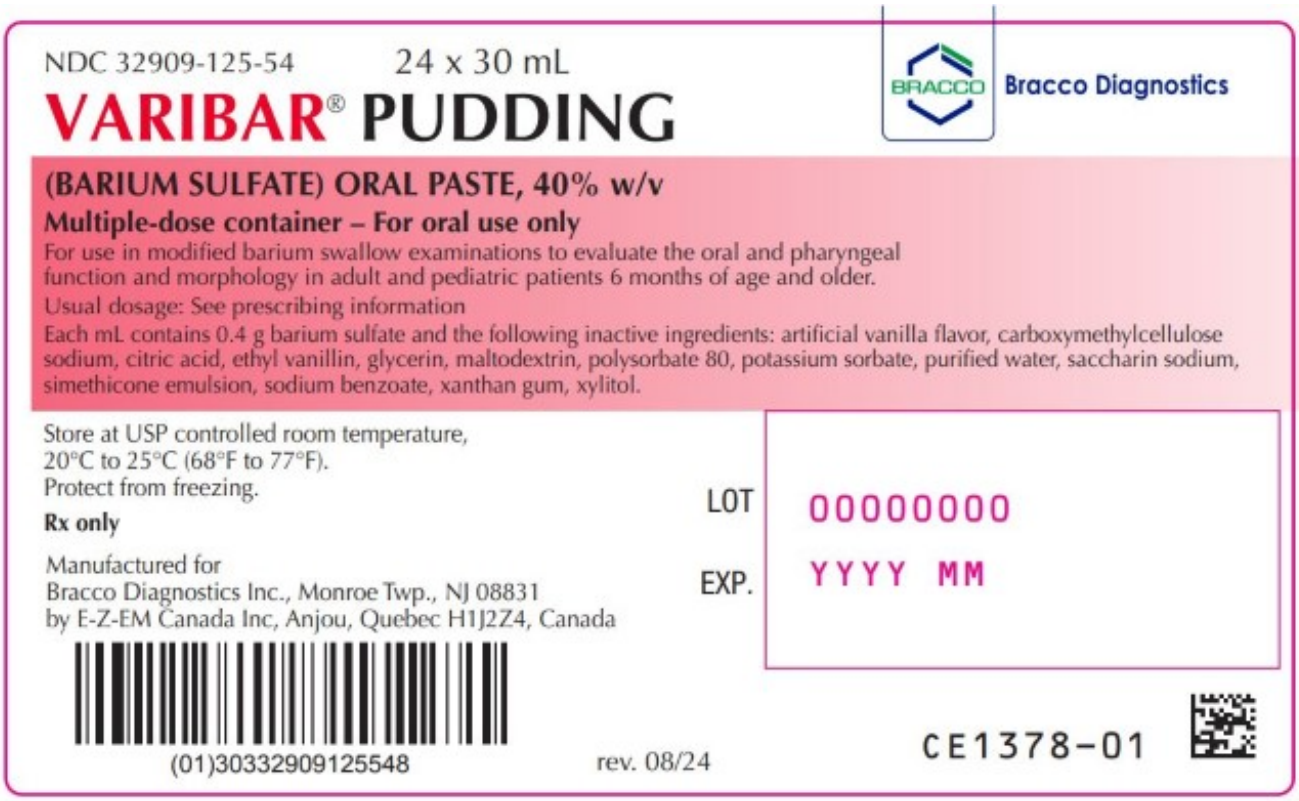
For Oral Use Only

Rx only

Manufactured for
Bracco Diagnostics Inc.
Monroe Twp., NJ 08831
by E-Z-EM Canada Inc.
Anjou, Québec H1J2Z4, Canada

FRONT

30 mL Varibar Pudding Label



30 mL Varibar Pudding Tube

VARIBAR PUDDING
barium sulfate paste

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:32909-125
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Barium Sulfate (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	400 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
DIMETHICONE 1000 (UNII: MCU2324216)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor	VANILLA	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:32909-125-22	1 in 1 BOX	10/14/2016	
1		230 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:32909-125-54	24 in 1 CASE	11/01/2024	
2		30 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208844	10/14/2016	

Labeler - E-Z-EM Canada Inc (204211163)

Registrant - E-Z-EM, INC. (002041226)

Establishment

Name	Address	ID/FEI	Business Operations
E-Z-EM Canada Inc		204211163	MANUFACTURE(32909-125) , PACK(32909-125) , LABEL(32909-125) , ANALYSIS(32909-125)

Revised: 11/2024 E-Z-EM Canada Inc