February 9, 2024

Dear Valued Customer,

As part of Bracco's long-term commitment to our customers, we would like to alert you of an upcoming product discontinuation that will be taking place in the Bracco barium portfolio. We are dedicated, as always, to providing you and your customers with barium products of the highest quality and outstanding service and support.

The streamlining of our product offerings is a result of a careful process during which we have analyzed potential redundancies and have ensured that specific barium products and procedures will continue to be available for the different gastrointestinal segments and imaging modalities using barium.

These updates will be communicated directly to our customers in the medical community in order to alleviate any confusion and help make this transition seamless with no break in the quality of care for their patients.

Discontinued Product

SKU	NDC	Product Name	Stock out date
902101	32909-770-01	E-Z-PASTE® BARIUM SULFATE ESOPHAGEAL CREAM (60% w/w)	March, 2024

E-Z-PASTE contrast is for use in single contrast radiography of the esophagus, pharynx, hypopharynx and cardiac series. Other currently approved Barium Sulfate Products are available as a substitute of E-Z-PASTE contrast to evaluate the esophagus, pharynx, and hypopharynx, as well as displacement or compression of the esophagus due to cardiovascular disease with three of the conventional 4-view cardiac series.

Substitution Products

SKU	NDC	Product Name
900006	32909-125-22	VARIBAR® PUDDING (barium sulfate) oral paste, 40% w/v
900005	32909-122-07	VARIBAR® HONEY (barium sulfate) oral suspension, 40% w/v
901901	32909-750-03	E-Z-PAQUE® (barium sulfate) 96% w/w
705693	32909-187-02	Liquid E-Z-PAQUE® (barium sulfate) oral suspension (60% w/v)

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If you have any questions relating to this matter, please feel free to contact me.

We thank you for your support and loyalty. Bracco is committed to your barium business, as we demonstrated with our acquisition of E-Z-EM, Inc. years ago. We would also like to thank all of our industry partners for their continued dedication to delivering safe, high-quality imaging to enhance patient care.

E-Z-PASTE® BARIUM SULFATE ESOPHAGEAL CREAM (60% w/w)

Indications and Usage:
E-Z-PASTE® BARIUM SULFATE ESOPHAGEAL CREAM (60% w/w) is for use in single contrast radiography of the esophagus, pharynx, hypopharynx, and for cardiac series.

IMPORTANT SAFETY INFORMATION:
For Oral Administration. This product should not be used in patients with known or suspected perforation of the GI tract, known obstruction of the GI tract, high risk of aspiration, or hypersensitivity to barium sulfate products. Rarely, severe allergic reactions of anaphylactoid nature have been reported following administration of barium sulfate contrast agents.

Please see full Prescribing Information for E-Z-PASTE BARIUM SULFATE ESOPHAGEAL CREAM (60% w/w) here.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

E-Z-PASTE is manufactured by E-Z-EM Canada Inc., for E-Z-EM, Inc., a subsidiary of Bracco Diagnostics Inc., Monroe Twp., NJ 08831.

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

VARIBAR® PUDDING (barium sulfate) oral paste, 40% w/v

INDICATION
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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
This product should not be used 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,

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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; or known hypersensitivity to barium sulfate or any of the excipients of VARIBAR® PUDDING (barium sulfate) oral paste.

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, 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.

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.

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. 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.

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. Monitor the patient closely for aspiration, discontinue administration of VARIBAR PUDDING if aspiration is suspected, and monitor for development of aspiration pneumonitis.

Systemic Embolization

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Barium sulfate products may occasionally 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. Although this complication is exceedingly uncommon after oral administration of a barium sulfate suspension, monitor patients for potential intravasation when administering barium sulfate.

ADVERSE REACTIONS
The most common adverse reactions are 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for full Prescribing Information for VARIBAR® PUDDING (barium sulfate) oral paste.

VARIBAR PUDDING is manufactured for Bracco Diagnostics Inc., Monroe Twp., NJ 08831 by E-Z-EM Canada Inc.

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

VARIBAR® HONEY (barium sulfate) oral suspension 40% w/v

INDICATION
VARIBAR® HONEY is a radiopaque 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
This product should not be used 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 of aspiration such as those with known or suspected tracheo-esophageal fistula or obtundation; or known severe hypersensitivity to barium sulfate or any of the excipients of VARIBAR HONEY.

WARNINGS AND PRECAUTIONS

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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.

Intra-abdominal Barium Leakage
The use of VARIBAR® HONEY (barium sulfate) oral suspension is contraindicated in patients at high risk of perforation of the GI tract. Administration of VARIBAR HONEY 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.

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. To reduce the risk of delayed GI transit and obstruction, patients should maintain adequate hydration after the barium sulfate procedure.

Aspiration Pneumonitis
The use of VARIBAR HONEY is contraindicated in patients with trachea-esophageal fistula. 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 HONEY. Monitor the patient closely for aspiration, discontinue administration of VARIBAR HONEY if aspiration is suspected, and monitor for development of aspiration pneumonitis.

Systemic Embolization
Barium sulfate products may occasionally 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. Although this complication is exceedingly uncommon after oral administration of a barium sulfate suspension, monitor patients for potential intravasation when administering barium sulfate.

ADVERSE REACTIONS
The most common adverse reactions are nausea, vomiting, diarrhea, and abdominal cramping. Serious adverse

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reactions and fatalities include aspiration pneumonitis, barium sulfate impaction, intestinal perforation with consequent peritonitis and granuloma formation, vasovagal and syncopal episodes.

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Please click here for full Prescribing Information for VARIBAR® HONEY (barium sulfate) oral suspension.

VARIBAR HONEY is manufactured by E-Z-EM Canada Inc., for Bracco Diagnostics Inc., Monroe Twp., NJ 08831.

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

E-Z-PAQUE® (barium sulfate) for oral suspension, 96% w/w

INDICATION
E-Z-PAQUE (barium sulfate) for oral suspension is indicated in adults and pediatrics for use in single contrast radiographic examinations of the esophagus, stomach, duodenum, and small bowel to visualize the gastrointestinal tract (GI).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
E-Z-PAQUE is contraindicated in patients with:
- known or suspected perforation of the 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 of aspiration such as those with prior aspiration, tracheoesophageal fistula, or obtundation
- known severe hypersensitivity to barium sulfate or any of the excipients of E-Z-PAQUE

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions
Barium sulfate preparations contain excipients, including natural and artificial flavors, and may induce serious hypersensitivity reactions which include hypotension, bronchospasm and other respiratory impairments, and 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.

Intra-abdominal Barium Leakage
Administration of E-Z-PAQUE may result in leakage of barium from the GI tract in the presence of

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conditions such as carcinomas, GI fistula, inflammatory bowel disease, gastric or duodenal ulcer, appendicitis, diverticulitis, and in patients with severe stenosis at any level of the GI tract, especially distal to the stomach. Barium leakage has been associated with peritonitis and granuloma formation.

Delayed Gastrointestinal Transit and Obstruction
Oral barium sulfate may accumulate proximal to a constricting lesion of the colon, causing obstruction or impaction with the development of baroliths (inspissated barium associated with feces) and may cause abdominal pain, appendicitis, bowel obstruction, or rarely perforation. Patients with severe stenosis at any level of the GI tract, impaired GI motility, electrolyte imbalance, dehydration, on a low residue diet, on medications that delay GI motility, constipation, cystic fibrosis, Hirschsprung disease, and the elderly are at higher risk for developing obstruction or baroliths. Maintain adequate hydration during and in the days following a barium sulfate procedure. Consider the administration of laxatives.

Aspiration Pneumonitis
Oral barium is associated with aspiration pneumonitis, especially in patients with a history of food aspiration or with compromised swallowing mechanisms. 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-PAQUE® (barium sulfate) for oral suspension. Discontinue administration of E-Z-PAQUE immediately if aspiration is suspected.

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. This complication is exceedingly uncommon after oral administration, monitor patients for potential intravasation when administering barium sulfate.

Risk with Hereditary Fructose Intolerance
E-Z-PAQUE contains sorbitol which may cause severe symptoms in patients with hereditary fructose intolerance including severe symptoms of vomiting, hypoglycemia, jaundice, hemorrhage, hepatomegaly, hyperuricemia, and kidney failure. Before administration of E-Z-PAQUE assess patients for a history of hereditary fructose intolerance and avoid use in these patients.

ADVERSE REACTIONS
The following adverse reactions have been identified from spontaneous reporting or clinical studies of orally administered barium sulfate:

- 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

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Please click here for full Prescribing Information for E-Z-PAQUE® (barium sulfate) for oral suspension.

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

Liquid E-Z-PAQUE® (barium sulfate) oral suspension (60% w/v)

INDICATION
Liquid E-Z-PAQUE (barium sulfate) oral suspension is indicated in adults and pediatrics for use in single contrast radiographic examinations of the esophagus, stomach, and small bowel to visualize the gastrointestinal tract (GI).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Liquid E-Z-PAQUE is contraindicated in patients with:

- known or suspected perforation of the 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 of aspiration such as those with prior aspiration, tracheoesophageal fistula, or obtundation
- known severe hypersensitivity to barium sulfate or any of the excipients of Liquid E-Z-PAQUE

WARNINGS AND PRECAUTIONS
Hypersensitivity Reactions
Barium sulfate preparations contain excipients, including natural and artificial flavors, and may induce serious hypersensitivity reactions which include hypotension, bronchospasm and other respiratory impairments, and 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.

Intra-abdominal Barium Leakage
Administration of Liquid E-Z-PAQUE 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, diverticulitis, and in patients with severe stenosis at any level of the GI tract, especially distal to the stomach. Barium leakage has been associated with peritonitis and granuloma formation.

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Delayed Gastrointestinal Transit and Obstruction
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Aspiration Pneumonitis
Oral barium is associated with aspiration pneumonitis, especially in patients with a history of food aspiration or with compromised swallowing mechanisms. 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 Liquid E-Z-PAQUE® (barium sulfate) oral suspension. Discontinue administration of Liquid E-Z-PAQUE immediately if aspiration is suspected.

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, monitor patients for potential intravasation when administering barium sulfate.

Risk with Hereditary Fructose Intolerance
Liquid E-Z-PAQUE contains sorbitol which may cause symptoms in patients with hereditary fructose intolerance including severe symptoms of vomiting, hypoglycemia, jaundice, hemorrhage, hepatomegaly, hyperuricemia, and kidney failure. Before administration of Liquid E-Z-PAQUE assess patients for a history of hereditary fructose intolerance and avoid use in these patients.

ADVERSE REACTIONS
The following adverse reactions have been identified from spontaneous reporting or clinical studies of orally administered barium sulfate:

- 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, and vasovagal and syncopal episodes.

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Sincerely,

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