

**READI-CAT 2- barium sulfate suspension**  
**READI-CAT 2 BANANA SMOOTHIE- barium sulfate suspension**  
**READI-CAT 2 BERRY SMOOTHIE- barium sulfate suspension**  
**READI-CAT 2 MOCHACCINO SMOOTHIE- barium sulfate suspension**  
**READI-CAT 2 CREAMY VANILLA SMOOTHIE- barium sulfate suspension**  
**E-Z-EM Canada Inc**

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**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use READI-CAT 2 and READI-CAT 2 SMOOTHIE products safely and effectively. See full prescribing information for READI-CAT 2 (barium sulfate) oral suspension  
READI-CAT 2 SMOOTHIE (barium sulfate) oral suspension  
Initial U.S. Approval: 2016

----- **RECENT MAJOR CHANGES** -----

Warning and Precautions (5.6) 2/2017

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

READI-CAT 2 and READI-CAT 2 SMOOTHIE are radiographic contrast agents, 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** -----

For oral use only:

- Adults and pediatric patients 12 years and older: 450 mL to 900 mL (9 g to 18 g of barium sulfate, respectively) (2.1)
- Patients younger than 12 years of age: scale down dose based on relative GI volume (2.1)

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

- Oral Suspension: 9 grams barium sulfate (2% w/v) supplied in a single dose HDPE plastic bottle (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 hypersensitivity to barium sulfate or any of the excipients of READI-CAT 2 products (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](http://www.fda.gov/medwatch).**

**See 17 for PATIENT COUNSELING INFORMATION.**

**Revised: 2/2017**

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

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## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

READI-CAT 2 and READI-CAT 2 SMOOTHIES are 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**

Base dosing on individual needs and procedure to be performed.

- Adult and pediatric patients 12 years and older: 450 mL to 900 mL (9 g to 18 g of barium sulfate)
- Patients younger than 12 years of age: adjust dose based on relative GI volume

#### **2.2 Administration Instructions**

- For oral use only
- Shake bottle vigorously for 30 seconds prior to oral administration
- Administer undiluted prior to scan
- Discard any unused suspension
- Advise patients to hydrate following the barium sulfate procedure

### **3 DOSAGE FORMS AND STRENGTHS**

Oral suspension: 9 grams of barium sulfate supplied as a suspension (2% w/v) in a single-dose HDPE plastic bottle.

### **4 CONTRAINDICATIONS**

READI-CAT 2 products are contraindicated in patients:

- with known or suspected perforation of the GI tract
- with 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 pelvis
- at 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 READI-CAT 2 or READI-CAT 2 SMOOTHIES

### **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 READI-CAT 2 products is contraindicated in patients at high risk of perforation of the GI tract [see *Contraindications (4)*]. Administration of READI-CAT 2 products 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, and 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 READI-CAT 2 products 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 READI-CAT 2 products. Discontinue administration of READI-CAT 2 products 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

READI-CAT 2 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 READI-CAT 2 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 USES IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

#### Risk Summary

READI-CAT 2 products are 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

READI-CAT 2 products are not absorbed systemically by the mother following oral administration, and breastfeeding is not expected to result in exposure of the infant to READI-CAT 2.

### 8.4 Pediatric Use

The efficacy of READI-CAT 2 in pediatric patients of all groups is based on successful opacification of the GI tract during radiographic procedures [see *Clinical Pharmacology (12.1)*].

READI-CAT 2 is contraindicated in pediatric patients with tracheo-esophageal fistula [see *Contraindications (4)*].

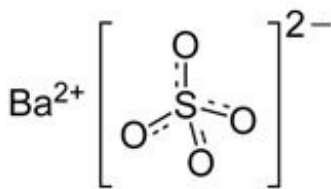
Pediatric patients with a history of asthma or food allergies may be at increased risk for development of hypersensitivity reactions [see *Warnings and Precautions (5.1)*]. Pediatric patients with cystic fibrosis or Hirschsprung disease should be monitored for bowel obstruction after use [see *Warnings and Precautions (5.3)*].

## 8.5 Geriatric Use

Clinical studies of READI-CAT 2 products 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

READI-CAT 2 and READI-CAT 2 SMOOTHIE (barium sulfate) are radiographic contrast agents supplied as a suspension (2% w/v) for oral administration. The active ingredient barium sulfate is designated chemically as BaSO<sub>4</sub> with a molecular weight of 233.4 g/mol, a density of 4.5 g/cm<sup>3</sup>, and the following chemical structure:



READI-CAT 2 products contain excipients including: benzoic acid, citric acid, potassium sorbate, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol solution, xanthan gum, and purified water.

READI-CAT 2 products also contain natural and artificial flavorings including: banana, blueberry, orange, vanilla, chocolate, and coffee flavors.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

Due to its high atomic number, barium (the active ingredient in READI-CAT 2 products) 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

READI-CAT 2 and READI-CAT 2 SMOOTHIES (barium sulfate) are supplied as suspensions (2 %

w/v) in a unit dose in a single-dose HDPE plastic bottle containing 9 grams of barium sulfate in 450 mL.

READI-CAT 2 products are provided in the following flavors as:

READI-CAT 2: (Orange): 12 x 450 mL bottles (NDC 32909-744-03)

READI-CAT 2 SMOOTHIE (Banana): 12 x 450 mL bottles (NDC 32909-742-03)

READI-CAT 2 SMOOTHIE (Berry): 12 x 450 mL bottles (NDC 32909-741-03)

READI-CAT 2 SMOOTHIE (Creamy Vanilla): 12 x 450 mL bottles (NDC 32909-746-03)

READI-CAT 2 SMOOTHIE (Mochaccino): 12 x 450 mL bottles (NDC 32909-747-03)

## **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.

Manufactured by

EZEM Canada Inc

Anjou (Quebec) Canada H1J 2Z4

For

Bracco Diagnostics Inc.

Monroe Township, NJ 08831

Revised January 2020

CL10E801

Readi-Cat<sup>®</sup> 2 Barium Sulfate Suspension Labels

NDC: 32909-744-03

NDC 32909-744-03

12 x 450 mL



Bracco Diagnostics

# READI-CAT® 2

## (BARIUM SULFATE) ORAL SUSPENSION (2% w/v)

Single dose bottle – For oral use only

For use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients. Usual dosage: See prescribing information

Each bottle contains 9 g barium sulfate and the following inactive ingredients:

Citric acid, natural and artificial orange flavor, natural and artificial vanilla flavor, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sorbitol, xanthan gum.

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

**Rx only**

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

LOT

EXP

Lot and expiry encoding area  
1" x 2"



(01)30332909744039

rev. 01/20

CE10E501



Single dose bottle – For oral use only

For use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients.

See prescribing information for complete dosage and administration information.

**SHAKE WELL PRIOR TO USE**

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

**DO NOT USE IF INNER SEAL IS BROKEN OR MISSING**

rev. 01/20

COMPUTED TOMOGRAPHY STUDIES



Bracco Diagnostics

450 mL

NDC 32909-744-03

# READI-CAT® 2

## (BARIUM SULFATE) ORAL SUSPENSION (2% w/v)



For Oral Use Only

**Rx only**

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

Each bottle contains 9 g barium sulfate and the following inactive ingredients: Citric acid, natural and artificial orange flavor, natural and artificial vanilla flavor, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sorbitol, xanthan gum.



(01)10332909744035

Lot

Exp

Lot and expiry encoding area  
Unvarnished



CI10E601

NDC 32909-742-03 12 x 450 mL

# BANANA SMOOTHIE READI-CAT® 2



Bracco Diagnostics

**(BARIUM SULFATE) ORAL SUSPENSION (2% w/v)**

**Single dose bottle – For oral use only**

For use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients.

Usual dosage: See prescribing information

Each bottle contains 9 g barium sulfate and the following inactive ingredients:

Artificial vanilla flavor, benzoic acid, citric acid, natural banana flavor, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol, xanthan gum.

Store at USP controlled room temperature,

20 to 25°C (68 to 77°F).

Protect from freezing.

**Rx only**

Manufactured for Bracco Diagnostics Inc.

Monroe Twp., NJ 08831

by E-Z-EM Canada Inc,

Anjou, Quebec H1J2Z4, Canada



(01)30332909742035

rev. 01/20

CE10E201



LOT

EXP

Lot and expiry encoding area

**Single dose bottle – For oral use only**

For use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients.

See prescribing information for complete dosage and administration information.

**SHAKE WELL PRIOR TO USE**

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

**DO NOT USE IF INNER SEAL IS BROKEN OR MISSING**

rev. 01/20

COMPUTED TOMOGRAPHY STUDIES



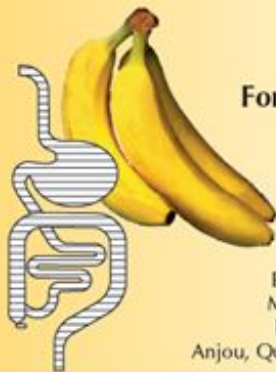
Bracco Diagnostics

450 mL

NDC 32909-742-03

# BANANA SMOOTHIE READI-CAT® 2

**(BARIUM SULFATE)  
ORAL SUSPENSION  
(2% w/v)**



**For Oral Use Only**

**Rx only**

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

Each bottle contains 9 g barium sulfate and the following inactive ingredients: Artificial vanilla flavor, benzoic acid, citric acid, natural banana flavor, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol, xanthan gum.



(01)10332909742031

Lot

Exp

Lot and expiry encoding area  
unvarnished



CI10E301

Readi-Cat® 2 Barium Sulfate Suspension Labels  
NDC: 32909-741-03



NDC 32909-741-03 12 x 450 mL

# BERRY SMOOTHIE READI-CAT® 2



Bracco Diagnostics

## (BARIUM SULFATE) ORAL SUSPENSION (2% w/v)

Single dose bottle – For oral use only

For use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients.

Usual dosage: See prescribing information

Each bottle contains 9 g barium sulfate and the following inactive ingredients:

Benzoic acid, citric acid, natural and artificial blueberry flavor, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol, xanthan gum.

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

**Rx only**

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

LOT

EXP

Lot/expiry encoding area



(01)30332909741038

rev. 01/20

CE10EC01



Single dose bottle – For oral use only

For use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients.

See prescribing information for complete dosage and administration information.

**SHAKE WELL PRIOR TO USE**

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

**DO NOT USE IF INNER SEAL IS BROKEN OR MISSING**

rev. 01/20



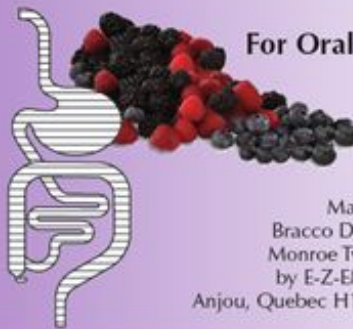
Bracco Diagnostics

450 mL

NDC 32909-741-03

# BERRY SMOOTHIE READI-CAT® 2

## (BARIUM SULFATE) ORAL SUSPENSION (2% w/v)



For Oral Use Only

**Rx only**

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

Each bottle contains 9 g barium sulfate and the following inactive ingredients: Benzoic acid, citric acid, natural and artificial blueberry flavor, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol, xanthan gum.

COMPUTED TOMOGRAPHY STUDIES



(01)10332909741034

Lot and expiry encoding area  
Unvarnished

Lot Exp



CI10ED01

NDC 32909-747-03 12 x 450 mL  
**MOCHACCINO SMOOTHIE  
 READI-CAT® 2**



**(BARIUM SULFATE) ORAL SUSPENSION (2% w/v)**

**Single dose bottle – For oral use only**

For use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients.  
 Usual dosage: See prescribing information

Each bottle contains 9 g barium sulfate and the following inactive ingredients: Benzoic acid, citric acid, natural and artificial bavarian chocolate flavor, natural and artificial coffee cappuccino flavor, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol, xanthan gum.

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

**Rx only**

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



(01)30332909747030

rev. 01/20

LOT

EXP

Lot and expiry encoding area

CE10E901



**Single dose bottle – For oral use only**

For use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients.

See prescribing information for complete dosage and administration information.

**SHAKE WELL PRIOR TO USE**

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

**DO NOT USE IF INNER SEAL IS BROKEN OR MISSING**

rev. 01/20

COMPUTED TOMOGRAPHY STUDIES



450 mL NDC 32909-747-03

**MOCHACCINO  
 SMOOTHIE  
 READI-CAT® 2**

**(BARIUM SULFATE)  
 ORAL SUSPENSION  
 (2% w/v)**

**For Oral Use Only**

**Rx only**



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

Each bottle contains 9 g barium sulfate and the following inactive ingredients: Benzoic acid, citric acid, natural and artificial bavarian chocolate flavor, natural and artificial coffee cappuccino flavor, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol, xanthan gum.



(01)10332909747036

Lot

Exp

Lot and expiry encoding area unvarnished



CI10EA01

Readi-Cat® 2 Barium Sulfate Suspension Labels  
 NDC: 32909-746-03

NDC 32909-746-03 12 x 450 mL  
**CREAMY VANILLA SMOOTHIE  
READI-CAT® 2**



Bracco Diagnostics

**(BARIUM SULFATE) ORAL SUSPENSION (2% w/v)**

**Single dose bottle – For oral use only**

For use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients.  
Usual dosage: See prescribing information

Each bottle contains 9 g barium sulfate and the following inactive ingredients: Artificial vanilla flavor, benzoic acid, citric acid, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol, xanthan gum.

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

**Rx only**

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

LOT

Lot/expiry encoding area

EXP



(01)30332909746033

rev. 01/20

CE10EF01



**Single dose bottle – For oral use only**

For use in computed tomography (CT) of the abdomen to delineate the gastrointestinal (GI) tract in adult and pediatric patients.

See prescribing information for complete dosage and administration information.

**SHAKE WELL PRIOR TO USE**

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

**DO NOT USE IF INNER SEAL IS BROKEN OR MISSING**

rev. 01/20

COMPUTED TOMOGRAPHY STUDIES



Bracco Diagnostics

450 mL NDC 32909-746-03

**CREAMY VANILLA  
SMOOTHIE  
READI-CAT® 2**

**(BARIUM SULFATE)  
ORAL SUSPENSION  
(2% w/v)**



**For Oral Use Only**

**Rx only**

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

Each bottle contains 9 g barium sulfate and the following inactive ingredients: Artificial vanilla flavor, benzoic acid, citric acid, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol, xanthan gum.



(01)10332909746039

Lot and expiry encoding area unvarnished

Lot

Exp



CI10F001

**READI-CAT 2**

barium sulfate suspension

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:32909-724
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Barium Sulfate (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	20 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
dimethicone 350 (UNII: 2Y53S6ATLU)	
dimethicone 1000 (UNII: MCU2324216)	
potassium sorbate (UNII: 1VPU26JZZ4)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0KO0R)	
xanthan gum (UNII: TTV12P4NEE)	
saccharin sodium (UNII: SB8ZUX40TY)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:32909-724-03	24 in 1 CARTON	03/27/2017	
1		450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208143	03/27/2017	05/31/2022

## READI-CAT 2 BANANA SMOOTHIE

barium sulfate suspension

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:32909-722
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Barium Sulfate</b> (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	20 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>benzoic acid</b> (UNII: 8SKN0B0MIM)	
<b>dimethicone 350</b> (UNII: 2Y53S6ATLU)	
<b>dimethicone 1000</b> (UNII: MCU2324216)	
<b>potassium sorbate</b> (UNII: 1VPU26JZZ4)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>trisodium citrate dihydrate</b> (UNII: B22547B95K)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>saccharin sodium</b> (UNII: SB8ZUX40TY)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BANANA, VANILLA	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:32909-722-03	24 in 1 CARTON	03/27/2017	04/30/2022
1		450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA208143	03/27/2017	04/30/2022

**READI-CAT 2 BERRY SMOOTHIE**

barium sulfate suspension

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:32909-711
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Barium Sulfate</b> (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	20 mg in 1 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>benzoic acid</b> (UNII: 8SKN0B0MIM)	
<b>dimethicone 350</b> (UNII: 2Y53S6ATLU)	
<b>dimethicone 1000</b> (UNII: MCU2324216)	
<b>potassium sorbate</b> (UNII: 1VPU26JZZ4)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>trisodium citrate dihydrate</b> (UNII: B22547B95K)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<b>water</b> (UNII: 059QF0K00R)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>saccharin sodium</b> (UNII: SB8ZUX40TY)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BLUEBERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:32909-711-03	24 in 1 CARTON	03/27/2017	04/30/2022
1		450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208143	03/27/2017	04/30/2022

# READI-CAT 2 MOCHACCINO SMOOTHIE

barium sulfate suspension

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:32909-777
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Barium Sulfate</b> (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	20 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>benzoic acid</b> (UNII: 8SKN0B0MIM)	
<b>dimethicone 350</b> (UNII: 2Y53S6ATLU)	
<b>dimethicone 1000</b> (UNII: MCU2324216)	
<b>potassium sorbate</b> (UNII: 1VPU26JZZ4)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>trisodium citrate dihydrate</b> (UNII: B22547B95K)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>saccharin sodium</b> (UNII: SB8ZUX40TY)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	COFFEE, CHOCOLATE	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:32909-777-03	24 in 1 CARTON	03/27/2017	03/31/2022
1		450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208143	03/27/2017	03/31/2022

## READI-CAT 2 CREAMY VANILLA SMOOTHIE

barium sulfate suspension

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:32909-756
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Barium Sulfate (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	20 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
benzoic acid (UNII: 8SKN0B0MIM)	
dimethicone 350 (UNII: 2Y53S6ATLU)	
dimethicone 1000 (UNII: MCU2324216)	
potassium sorbate (UNII: 1VPU26JZZ4)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium benzoate (UNII: OJ245FE5EU)	
trisodium citrate dihydrate (UNII: B22547B95K)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0KO0R)	
xanthan gum (UNII: TTV12P4NEE)	
saccharin sodium (UNII: SB8ZUX40TY)	

### 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:32909-756-03	24 in 1 CARTON	03/27/2017	04/30/2022
1		450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208143	03/27/2017	04/30/2022

## READI-CAT 2

barium sulfate suspension

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:32909-744
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Barium Sulfate (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	20 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
dimethicone 350 (UNII: 2Y53S6ATLU)	
dimethicone 1000 (UNII: MCU2324216)	
potassium sorbate (UNII: 1VPU26JZZ4)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0K00R)	
xanthan gum (UNII: TTV12P4NEE)	
saccharin sodium (UNII: SB8ZUX40TY)	

### Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:32909-744-03	12 in 1 CARTON	11/01/2020	
1		450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208143	11/01/2020	

## READI-CAT 2 BANANA SMOOTHIE

barium sulfate suspension

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:32909-742
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Barium Sulfate (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	20 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
benzoic acid (UNII: 8SKN0B0MIM)	
dimethicone 350 (UNII: 2Y53S6ATLU)	
dimethicone 1000 (UNII: MCU2324216)	
potassium sorbate (UNII: 1VPU26JZZ4)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium benzoate (UNII: OJ245FE5EU)	
trisodium citrate dihydrate (UNII: B22547B95K)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0KO0R)	
xanthan gum (UNII: TTV12P4NEE)	
saccharin sodium (UNII: SB8ZUX40TY)	

### Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	BANANA, VANILLA	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:32909-742-03	12 in 1 CARTON	11/01/2020	

1	450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208143	11/01/2020	

## READI-CAT 2 BERRY SMOOTHIE

barium sulfate suspension

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:32909-741
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Barium Sulfate (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	20 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
benzoic acid (UNII: 8SKN0B0MIM)	
dimethicone 350 (UNII: 2Y53S6ATLU)	
dimethicone 1000 (UNII: MCU2324216)	
potassium sorbate (UNII: 1VPU26JZZ4)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium benzoate (UNII: OJ245FE5EU)	
trisodium citrate dihydrate (UNII: B22547B95K)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0KO0R)	
xanthan gum (UNII: TTV12P4NEE)	
saccharin sodium (UNII: SB8ZUX40TY)	

### Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	BLUEBERRY	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:32909-741-03	12 in 1 CARTON	11/01/2020	
1		450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208143	11/01/2020	

## READI-CAT 2 MOCHACCINO SMOOTHIE

barium sulfate suspension

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:32909-747
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Barium Sulfate (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	20 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
benzoic acid (UNII: 8SKN0B0MIM)	
dimethicone 350 (UNII: 2Y53S6ATLU)	
dimethicone 1000 (UNII: MCU2324216)	
potassium sorbate (UNII: 1VPU26JZZ4)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium benzoate (UNII: OJ245FE5EU)	
trisodium citrate dihydrate (UNII: B22547B95K)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0K00R)	
xanthan gum (UNII: TTV12P4NEE)	
saccharin sodium (UNII: SB8ZUX40TY)	

### Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	COFFEE, CHOCOLATE	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:32909-747-03	12 in 1 CARTON	11/01/2020	
1		450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208143	11/01/2020	

## READI-CAT 2 CREAMY VANILLA SMOOTHIE

barium sulfate suspension

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:32909-746
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Barium Sulfate (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	20 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
benzoic acid (UNII: 8SKN0B0MIM)	
dimethicone 350 (UNII: 2Y53S6ATLU)	
dimethicone 1000 (UNII: MCU2324216)	
potassium sorbate (UNII: 1VPU26JZZ4)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium benzoate (UNII: OJ245FE5EU)	
trisodium citrate dihydrate (UNII: B22547B95K)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0K00R)	
xanthan gum (UNII: TTV12P4NEE)	
saccharin sodium (UNII: SB8ZUX40TY)	

### 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:32909-746-03	12 in 1 CARTON	11/01/2020	
1		450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208143	11/01/2020	

**Labeler** - E-Z-EM Canada Inc (204211163)**Registrant** - BRACCO DIAGNOSTICS INC (849234661)**Establishment**

Name	Address	ID/FEI	Business Operations
E-Z-EM Canada Inc		204211163	ANALYSIS(32909-746, 32909-777, 32909-711, 32909-747, 32909-722, 32909-756, 32909-742, 32909-741, 32909-724, 32909-744), MANUFACTURE(32909-711, 32909-742, 32909-777, 32909-741, 32909-722, 32909-747, 32909-756, 32909-744, 32909-746, 32909-724)

Revised: 10/2020

E-Z-EM Canada Inc