NDC 32909-723-01, 32909-723-02, 32909-723-03
READI-CAT® 2
BARIUM SULFATE SUSPENSION
(2.1% w/v, 2.0% w/w)

NDC 32909-735-03
APPLE SMOOTHIE
READI-CAT® 2

NDC 32909-725-07, 32909-725-03
BANANA SMOOTHIE
READI-CAT® 2

NDC 32909-755-07, 32909-755-03
CREAMY VANILLA SMOOTHIE
READI-CAT® 2

NDC 32909-715-03
BERRY SMOOTHIE
READI-CAT® 2

NDC 32909-775-03
MOCHACCINO SMOOTHIE
READI-CAT® 2

NDC 32909-728-01, 32909-728-02, 32909-728-03, 32909-410-01
READI-CAT and CAT-PAK
Filled with READI-CAT
BARIUM SULFATE SUSPENSION
(1.3% w/v, 1.2% w/w)

DESCRIPTION: READI-CAT® 2 is a barium sulfate suspension 2.1% w/v, 2.0% w/w for oral and rectal administration. Each 100 mL contains 2.1 g barium sulfate. Barium sulfate, due to its high molecular density is opaque to x-rays and therefore, acts as a positive contrast agent for radiographic studies. The active ingredient is barium sulfate and its structural formula is $BaSO_4$. Barium sulfate occurs as a fine, white, odorless, tasteless, bulky powder which is free from grittiness. Its aqueous suspensions are neutral to litmus. It is practically insoluble in water, solutions of acids and alkalies, and organic solvents.

Inactive Ingredients: citric acid, natural gum, natural and artificial orange flavor, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sorbitol and natural and artificial vanilla flavor.

APPLE SMOOTHIE READI-CAT® 2 is a barium sulfate suspension 2.1% w/v, 2.0% w/w for oral administration. Each 100 mL contains 2.1 g barium sulfate. Barium sulfate, due to its high molecular density is opaque to x-rays and therefore, acts as a positive contrast agent for radiographic studies. The active ingredient is barium sulfate and its structural formula is $BaSO_4$. Barium sulfate occurs as a fine, white, odorless, tasteless, bulky powder which is free from grittiness. Its aqueous suspensions are neutral to litmus. It is practically insoluble in water, solutions of acids and alkalies, and organic solvents.

Inactive Ingredients: natural and artificial apple flavor, benzoic acid, citric acid, natural gum, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, and sorbitol.

BANANA SMOOTHIE READI-CAT® 2 is a barium sulfate suspension 2.1% w/v, 2.0% w/w for oral administration. Each 100 mL contains 2.1 g barium sulfate. Barium sulfate, due to its high molecular density is opaque to x-rays and therefore, acts as a positive contrast agent for radiographic studies. The active ingredient is barium sulfate and its structural formula is $BaSO_4$. Barium sulfate occurs as a fine, white, odorless, tasteless, bulky powder which is free from grittiness. Its aqueous suspensions are neutral to litmus. It is practically insoluble in water, solutions of acids and alkalies, and organic solvents.

Inactive Ingredients: benzoic acid, natural gum, natural banana flavor (with other natural flavors), potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol and artificial vanilla flavor.

CREAMY VANILLA SMOOTHIE READI-CAT® 2 is a barium sulfate suspension 2.1% w/v, 2.0% w/w for oral administration. Each 100 mL contains 2.1 g barium sulfate. Barium sulfate, due to its high molecular density is opaque to x-rays and therefore, acts as a positive contrast agent for radiographic studies. The active ingredient is barium sulfate and its structural formula is $BaSO_4$. Barium sulfate occurs as a fine, white, odorless, tasteless, bulky powder which is free from grittiness. Its aqueous suspensions are neutral to litmus. It is practically insoluble in water, solutions of acids and alkalies, and organic solvents.

Inactive Ingredients: benzoic acid, citric acid, natural gum, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, sorbitol and artificial vanilla flavor.

BERRY SMOOTHIE READI-CAT® 2 is a barium sulfate suspension 2.1% w/v, 2.0% w/w for oral administration. Each 100 mL contains 2.1 g barium sulfate. Barium sulfate, due to its high molecular density is opaque to x-rays and therefore, acts as a positive contrast agent for radiographic studies. The active ingredient is barium sulfate and its structural formula is $BaSO_4$. Barium sulfate occurs as a fine, white, odorless, tasteless, bulky powder which is free from grittiness. Its aqueous suspensions are neutral to litmus. It is practically insoluble in water, solutions of acids and alkalies, and organic solvents.

Inactive Ingredients: benzoic acid, natural and artificial blueberry flavor, citric acid, natural gum, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, and sorbitol.

MOCHACCINO SMOOTHIE READI-CAT® 2 is a barium sulfate suspension 2.1% w/v, 2.0% w/w for oral administration. Each 100 mL contains 2.1 g barium sulfate. Barium sulfate, due to its high molecular density is opaque to x-rays and therefore, acts as a positive contrast agent for radiographic studies. The active ingredient is barium sulfate and its structural formula is $BaSO_4$. Barium sulfate occurs as a fine, white, odorless, tasteless, bulky powder which is free from grittiness. Its aqueous suspensions are neutral to litmus. It is practically insoluble in water, solutions of acids and alkalies, and organic solvents.

Inactive Ingredients: natural and artificial bavarian chocolate flavor, benzoic acid, natural and artificial coffee cappuccino flavor, citric acid, natural gum, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, and sorbitol.

READI-CAT® is a barium sulfate suspension 1.3% w/v, 1.2% w/w for oral and rectal administration. Each 100 mL contains 1.3 g barium sulfate. Barium sulfate, due to its high molecular density is opaque to x-rays and therefore, acts as a positive contrast agent for radiographic studies. The active ingredient is barium sulfate and its structural formula is $BaSO_4$. Barium sulfate occurs as a fine, white, odorless, tasteless, bulky powder which is free from grittiness. Its aqueous suspensions are neutral to litmus. It is practically insoluble in water, solutions of acids and alkalies, and organic solvents.

Inactive Ingredients: citric acid, natural gum, natural and artificial orange flavor, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sorbitol and natural and artificial vanilla flavor.

CLINICAL PHARMACOLOGY: Barium sulfate, due to its high molecular density is opaque to x-rays and, therefore, acts as a positive contrast agent for radiographic studies. Barium sulfate is biologically inert and, therefore, is not absorbed or metabolized by the body, and is eliminated from the GI tract unchanged.

INDICATIONS AND USAGE: For use in Computed Tomography to opacify the GI tract.

CONTRAINDICATIONS: For oral administration: This product should not be used in patients with known or suspected gastric or intestinal perforation, or hypersensitivity to barium sulfate or any component of this barium sulfate formulation.

Contraindications for CAT-PAK™: For rectal administration: This product should not be used in patients with known or suspected intestinal perforation, toxic megacolon; or hypersensitivity to barium sulfate or any component of this barium sulfate formulation. It should not be used within six days of large forceps or "hot" colonic biopsy, or a snare polypectomy. Do not use this product in a colostomy stoma, which requires a special colostomy catheter that is available from E-Z-EM. Do not use a retention cuff following recent rectal surgery or low rectal anastomosis, or when proctitis or other rectal conditions such as inflammatory or neoplastic diseases are suspected. A retention cuff is not necessary or desirable in patients with normal sphincter tone, which can be determined by preliminary rectal digital examination.

WARNINGS: Rarely, severe allergic reactions of an anaphylactoid nature, have been reported following administration of barium sulfate contrast agents. Appropriately trained personnel and facilities should be available for emergency treatment of severe reactions and should remain available for at least 30 to 60 minutes following administration, since delayed reactions can occur.

PRECAUTIONS: General: Diagnostic procedures which involve the use of radiopaque contrast agents should be carried out under the direction of personnel with the requisite training and with a thorough knowledge of the particular procedure to be performed. A history of bronchial asthma, atopy, as evidenced by hay fever and eczema, or a previous reaction to a contrast agent, warrant special attention. Caution should be exercised with the use of radiopaque media in severely debilitated patients and in those with marked hypertension or advanced cardiac disease. Ingestion of barium is not recommended in patients with a history of food aspiration. If barium studies are required in these patients or in patients in whom integrity of the swallowing mechanism is unknown, proceed with caution. If

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barium is aspirated into the larynx, further administration should be immediately discontinued. After any barium study of the GI tract, it is important to rehydrate the patient as quickly as possible to prevent impaction of the barium. To prevent barium impaction in the colon, the use of mild laxatives such as milk of magnesia or lactulose following completion of the examination may also be required. These mild laxatives are recommended on a routine basis and in patients with a history of constipation unless clinically contraindicated.

Precaution for CAT-PAK™: Use with caution during rectal administration when obstructive lesions of the colon are suspected. Care should be taken to minimize the amount of barium sulfate allowed to flow proximal to obstructive lesions of the colon. Care must be taken during insertion of the enema tip into the patient to prevent application of pressure to the vagus nerve, which can lead to vasovagal reactions and syncopal episodes. Forceful or deep insertion may also cause tearing or perforation of the rectum.

Information for Patients: Before using this product patients should be instructed to tell the physician ordering the procedure and the imaging technologist:

1. if they are pregnant.
2. if they are allergic to any foods or medication, or if they have had any prior reactions to barium sulfate products or other x-ray contrast agents.
3. if they are currently taking any medications, have any serious medical condition for which they are being treated or followed, or had any recent surgery.
4. seek immediate medical attention if they experience an allergic reaction after using this product.

Drug Interactions: The presence of barium sulfate formulations in the GI tract may alter the absorption of therapeutic agents taken concomitantly. In order to minimize any potential change in absorption, the separate administration of barium sulfate from that of other agents should be considered.

Usage in Pregnancy: Radiation is known to cause harm to the unborn fetus exposed *in utero*. Therefore, radiographic procedures should only be used when, in the judgement of the physician, its use is deemed essential to the welfare of the pregnant patient.

Nursing Mothers: Barium sulfate products may be used during lactation.

ADVERSE REACTIONS: Adverse reactions, such as nausea, vomiting, diarrhea and abdominal cramping, accompanying the use of barium sulfate formulations are infrequent and usually mild. Severe reactions (approximately 1 in 1,000,000) and fatalities (approximately 1 in 10,000,000) have occurred. Procedural complications are rare, but may include aspiration pneumonitis, barium impaction, granuloma formation, intravasation, embolization and peritonitis following intestinal perforation, vasovagal and syncopal episodes, and fatalities. EKG changes have been reported following or during barium enema procedures. It is of the utmost importance to be completely prepared to treat any such occurrence.

ALLERGIC REACTIONS: Due to the increased likelihood of allergic reactions in atopic patients, it is important that a complete history of known and suspected allergies as well as allergic-like symptoms, e.g., rhinitis, bronchial asthma, eczema and urticaria, must be obtained prior to any medical procedure utilizing these products. A mild allergic reaction would most likely include generalized pruritus, erythema or urticaria (approximately 1 in 250,000). Such reactions will generally respond to an antihistamine such as 50 mg of diphenhydramine or its equivalent. In the rarer, more serious reactions (approximately 1 in 1,000,000) laryngeal edema, bronchospasm or hypotension could develop. Severe reactions which may require emergency measures are often characterized by peripheral vasodilation, hypotension, reflex tachycardia, dyspnea, agitation, confusion and cyanosis, progressing to unconsciousness. Treatment should be initiated immediately with 0.3 to 0.5 cc of 1:1000 epinephrine subcutaneously. If bronchospasm predominates, 0.25 to 0.50 grams of intravenous aminophylline should be given slowly. Appropriate vasopressors might be required. Adrenocorticosteroids, even if given intravenously, exert no significant effect on the acute allergic reactions for a few hours. The administration of these agents should not be regarded as emergency measures for the treatment of allergic reactions.

Apprehensive patients may develop weakness, pallor, tinnitus, diaphoresis and bradycardia following the administration of any diagnostic agent. Such reactions are usually non-allergic in nature and are best treated by having the patient lie flat for an additional 10 to 30 minutes under observation.

All E-Z-EM barium sulfate contrast and barium contrast delivery systems are latex-free. However, allergic reactions to enema accessories, in particular to other manufacturers' retention catheters (tips) with a latex cuff, can occur. Such reactions could occur immediately and result in acute allergic-like responses or might be delayed in appearance and result in a contact dermatitis. Known atopic patients, particularly those with a history of asthma or eczema, should be evaluated for alternative methods of administration in order to avoid these adverse reactions. All plastic/rubber accessories are disposable, single-use devices that must not be reused or left in the body cavity for an extended period of time.

OVERDOSAGE: On rare occasions following repeated administration, severe stomach cramps, nausea, vomiting, diarrhea or constipation may occur. These indicated responses can be present in both fluoroscopic and CT procedures. These are transitory in nature and are not considered serious. Symptoms may be treated according to currently accepted standards of medical care.

DOSAGE AND ADMINISTRATION: The volume and concentration of the CT barium sulfate suspension to be administered will depend on the degree and extent of contrast required in the area(s) under examination and on the equipment and technique employed.

For Rectal Administration: Special Instructions for CAT-PAK: Lubricate enema tip with desired lubricant. Carefully insert tip under fluoroscopic guidance. This should be performed only by a physician or qualified personnel under a physician's supervision. Administer barium sulfate in accordance with the suggested protocols below, taking care to avoid unnecessarily moving enema tip once it has been inserted. Gently remove and discard the tip and the entire CAT-PAK system. (These are intended for single use only).

Suggested Protocol for Pelvis Studies: Administer 300 mL to 400 mL rectally using CAT-PAK (Cat. No. P410).

Suggested 30 minute Barium Administration Protocol for Abdomen/Pelvis Studies: Administer 300 mL to 400 mL rectally using the CAT-PAK (Cat. No. P410).

For Oral Administration: Suggested 30 Minute Barium Administration Protocol for Abdomen Studies: Administer 300 mL CT barium suspension 30 minutes before scan and 150 mL immediately prior to scan; or use as directed by physician.

Suggested 90 Minute Barium Administration Protocol for Abdomen/Pelvis Studies: Administer 450 mL CT barium suspension 90 minutes before scan, another 300 mL 30 minutes before scan, and finally 150 mL immediately prior to scan; or use as directed by physician.

Other dosing regimens may be followed as applicable.

STORAGE: Store product to protect from freezing and excessive heat (above 40°C).

HOW SUPPLIED:
READI-CAT® 2 is supplied in the following quantities:
450 mL bottles, Cat. No. 723, NDC 32909-723-01;
900 mL jugs, Cat. No. 729, NDC 32909-723-03;
1900 mL jugs, Cat. No. 726, NDC 32909-723-02.

APPLE SMOOTHIE READI-CAT® 2 is supplied in the following quantities:
450 mL bottles, Cat. No. 7350, NDC 32909-735-03.

BANANA SMOOTHIE READI-CAT® 2 is supplied in the following quantities:
250 mL bottles; Cat. No. 7250, NDC 32909-725-07;
450 mL bottles, Cat. No. 7450, NDC 32909-725-03.

CREAMY VANILLA READI-CAT® 2 is supplied in the following quantities:
250 mL bottles; Cat. No. 7650, NDC 32909-755-07;
450 mL bottles, Cat. No. 7550, NDC 32909-755-03.

BERRY SMOOTHIE READI-CAT® 2 is supplied in the following quantities:
450 mL bottles, Cat. No. 7150, NDC 32909-715-03.

MOCHACCINO SMOOTHIE READI-CAT® 2 is supplied in the following quantities:
450 mL bottles, Cat. No. 450307, NDC 32909-775-03.

READI-CAT® is supplied in the following quantities:
450 mL bottles, Cat. No. 728, NDC 32909-728-01;
900 mL jugs, Cat. No. 721, NDC 32909-728-03;
1900 mL jugs, Cat. No. 724, NDC 32909-728-02.

CAT-PAK™ filled with READI-CAT® a is supplied in the following manner:
as a kit, Cat. No. P410
NDC 32909-410-01, includes 400 mL bottle; Cat.No. P410,
NDC 32909-411-01; and tubing set with a rigid tip.

Applicable CPT Codes: 74160, 72193

℞ Only (USA)

SHAKE WELL PRIOR TO USE

Manufactured by E-Z-EM Canada Inc.,
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EZ EM®

NOM DU PRODUIT / PRODUCT NAME:	READI-CAT 2
NUMÉRO DU PRODUIT / PRODUCT NUMBER:	TX1167-6
DIMENSIONS (MM): À PLAT / FLAT:	215,9 X 279,4
PLIÉ / FOLDED:	215,9 X 140
CODE À BARRE / BARCODE:	TX1167-6

COULEUR(S) / COLOR(S):

#1 F B

BLACK/NOIR