E-Z-DOSE™ WITH LIQUID POLIBAR PLUS®
BARIUM SULFATE SUSPENSION
(105% w/v, 58% w/w)

DESCRIPTION
E-Z-DOSE™ with LIQUID POLIBAR PLUS® is a single dose, disposable barium sulfate retention enema system which includes the Miller™ Air tip. E-Z-DOSE™ with LIQUID POLIBAR PLUS® contains barium sulfate suspension (105% w/v, 58% w/w) for rectal administration. Each 100 mL contains 105 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 \(\text{BaSO}_4\). 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
acacia, citric acid, hydrochloric acid, natural and artificial vanilla flavor, polysorbate 80, potassium chloride, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium carrageenan, sodium citrate, sorbitol solution and xanthan gum.

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 unchanged from the body.

INDICATIONS AND USAGE
For radiography of the gastrointestinal tract.

CONTRAINDICATIONS
This product should not be used in patients with known intestinal perforation or hypersensitivity to barium sulfate products.

Enema System
Do not use a retention cuff in a colostomy stoma. A colostomy stoma requires a special colostomy catheter. 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. In those cases use soft pediatric Flexi-Tip® rectal catheters, E-Z-EM Ref. 9504 (24 Fr) or Ref. 9514 (14 Fr).

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.

Barium sulfate should not be used proximal to known or suspected obstruction of the colon, or in those cases where the use of barium sulfate is contraindicated. Care must be taken to avoid overinflation of the cuff, since overfilling, or asymmetrical filling with displacement of the tip, may occur. Such displacement can lead to rectal perforation, barium granulomas or vasovagal reactions, or may cause the cuff to deflate. Overinflation may cause the inflatable cuff to rupture with possible injury to the patient. The enema tip should also not be moved unnecessarily once inserted.

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.

After any barium study of the GI tract, it is important to rehydrate the patient as quickly as possible to prevent impaction of the bowel by barium sulfate. To prevent barium sulfate impaction in the bowel, 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 contraindicated.

Inflation of the retention cuff should only be performed by a physician, or qualified personnel under a physician’s supervision, under fluoroscopic control. Do not inflate cuff with more than 100 cc air. Use only with the E-Z-EM Retention Cuff Inflator Ref. 9529. Do not unnecessarily move enema tip and inflated retention cuff once inserted. To ensure maximum rectal visualization, the inflated cuff should be deflated immediately after completion of the fluoroscopic phase of the exam, or after the colon is completely filled.

Information for Patients

Before administration of this product patients should be instructed to:
1. Inform their physician if they are pregnant.
2. Inform their physician if they are allergic to any drugs or food, or if they have had any prior reactions to barium sulfate products or other contrast agents used in x-ray procedures (see PRECAUTIONS - General).
3. Inform their physician about any other medications they are currently taking.

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, their 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 sulfate 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 mL 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 contrast and barium contrast delivery systems are latex-free. However, allergic reactions to enema accessories, in particular to retention catheters (tips) with latex cuffs, can occur. Such reactions could occur immediately and result in the previously mentioned 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 are transitory in nature and are not considered serious. Symptoms may be treated according to currently accepted standards of medical care.

**DOSAGE AND ADMINISTRATION**
General

The volume and concentration of LIQUID POLIBAR PLUS® 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. See below for typical adult doses.

Patient Preparation for Colon Examinations

In order to achieve optimum results, the colon must be cleansed prior to the use of a barium enema. This is usually accomplished by placing the patient on a low fat, low residue diet, combined with the use of laxatives and/or cathartics. A cleansing enema may also be used unless contraindicated.

Double-Contrast Colon Examination (if other enema tips, inflators or insufflators are used refer to their labeling for directions for use)

The following procedure is intended only as a guide. The quantity of contrast to use will depend on the patient’s body habits and the radiographic procedures being preferred (typical adult dose: 500 mL to 1500 mL).

- Attach the Retention Cuff Inflator (E-Z-EM Ref. 9529) to the clear tube on the retention cuff.
- Attach the blue air-bulb insufflator (E-Z-EM Ref. 9525) to the blue tube.
- Inspect the tubing system to ensure that it is free of obstructions.
- Shake bottle VIGOROUSLY prior to use. Close off the large-bore tubing with the clamp and attach it securely to the bottle.
- Suspend the bottle and bleed air from the tubing. Reclamp.
- Lubricate the enema tip with desired lubricant and carefully insert. Carefully insert the tip until the base of the retention cuff is just beyond the anorectal junction. The base of the cuff should be at the level of anal sphincter for best retention and maximum safety. If necessary, the cuff should be gently pulled back until its proximal end rests on the anal sphincter.
- Note: A retention cuff is not necessary or desirable in patients with normal sphincter tone. This can be determined by preliminary rectal digital examination.
- Prior to inflating the retention cuff, fluoroscopy may be used to visualize the rectum with contrast medium to ensure the absence of contraindications. (See CONTRAINDICATIONS).
- Inflate the cuff under fluoroscopic control. Use only the Retention Cuff Inflator (E-Z-EM Ref. 9529) to inflate retention cuff with approximately 100 cc air. To inflate the cuff, squeeze inflator once only and clamp off the tubing to retain inflation. (See PRECAUTIONS).
- Start with patient in the prone position. Fill the rectum with LIQUID POLIBAR PLUS®
- Rotate the patient (left side down and 10° to 15° Trendelenberg) and introduce enough LIQUID POLIBAR PLUS® to reach the splenic flexure. Clamp tubing shut.
- Rotate the patient to the prone position, with the bottle on the floor, drain the rectum. Clamp the tubing and introduce air to inflate ascending colon and cecum.
- Turn the patient slowly to the right side and introduce more air. (Evacuate rectum again if necessary).
- Turn the patient slowly on his/her back. This maneuver will cause barium to pass through the hepatic flexure into the ascending colon.
- Slowly turn the patient to the prone position and raise the table slightly. Doing this will fill the cecum. If necessary, drain the rectum and introduce additional air.
- To remove the enema tip, deflate the cuff by releasing the clamp on the Retention Cuff Inflator. Gently remove and discard the tip and the entire E-Z-DOSE™ system.

STORAGE

USP Controlled Room Temperature, 20 to 25°C (68 to 77°F). Protect from freezing.
HOW SUPPLIED

E-Z-DOSE™ is supplied as follows:
As a kit, Cat. No. P650PPS, NDC 32909-652-02, which includes 650 mL bottle Cat. No. P650PPS, NDC 32909-651-01 and tubing with a Miller™ Air Tip.

Rx Only (USA)

SHAKE WELL PRIOR TO USE

Manufactured by
a subsidiary of Bracco Diagnostics Inc.
Monroe Township, NJ 08831
Tel: 1-516-333-8230 1-800 544-4624
rev. 08/14TX1739

E-Z-Dose with Liquid Polibar Plus - Package
NDC: 32909-652-02

E-Z-Dose with Liquid Polibar Plus - Package
NDC: 32909-652-02

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Route of Administration: RECTAL

Active Ingredient/Active Moiety

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E-Z-EM Canada Inc

**Product Characteristics**

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**Packaging**

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**Marketing Information**

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**Labeler** - E-Z-EM Canada Inc (20421163)

**Registrant** - E-Z-EM, INC. (00204126)

**Establishment**

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Revised: 2/2015

E-Z-EM Canada Inc