

LIQUID POLIBAR PLUS- barium sulfate suspension
E-Z-EM Canada Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

LIQUID POLIBAR PLUS®
BARIUM SULFATE SUSPENSION
(105% w/v, 58% w/w)

DESCRIPTION

LIQUID POLIBAR PLUS® Barium Sulfate Suspension (105% w/v, 58% w/w) is a barium sulfate suspension for oral and 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 BaSO₄. 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

Oral Administration

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

Rectal Administration

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

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 this product 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 this product 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 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.

Oral Administration

Use with caution in patient with complete or nearly complete obstruction of the gastrointestinal tract.

Rectal Administration

Use with caution 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. When used rectally, care must be taken during insertion of the enema tip into the patient, since forceful or too deep insertion may cause tearing or perforation of the rectum.

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 applicable system below for typical adult dose.

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.

RECTAL ADMINISTRATION

In order to assure rapid colonic filling and drainage, LIQUID POLIBAR PLUS[®] should only be used with an enema kit with a large (½ inch) lumen such as the Super XL[®] Enema Bag System (Cat. No. 8925) or equivalent. Refer to the enema kit labeling for additional CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and INSTRUCTIONS FOR USE. Refer to manufacturer's instructions if another administration system is used.

Single Contrast Colon Studies

Dilute 1 part LIQUID POLIBAR PLUS[®] with 5 parts water to yield approximately 17.5% w/v, 15% w/w; or dilute as required.

Typical Adult Dose: 1000 mL to 2500 mL of diluted suspension.

Double Contrast Colon Studies

Use undiluted.

Typical Adult Dose: 500 mL to 1500 mL or as directed by a physician.

ORAL ADMINISTRATION

Esophagus and Cardiac Series

Undiluted LIQUID POLIBAR PLUS[®] should be administered orally for double-contrast examination of the esophagus. Films are taken during rapid swallowing of barium sulfate.

Typical Adult Dose: 60 mL to 300 mL

Stomach

LIQUID POLIBAR PLUS[®] can be used for single or double-contrast examination of the stomach. It can be used undiluted or diluted 1:1 with water to produce a 52.5% w/v. Diluted LIQUID POLIBAR PLUS[®] is highly suited for a biphasic examination of the stomach. Following completion of the double-contrast examination of the stomach using E-Z-HD[™] barium sulfate, undiluted or diluted 1:1 with water, LIQUID POLIBAR PLUS[®] may be used for the single phase of the study.

Typical Adult Dose: 150 mL to 340 mL of diluted or undiluted as applicable.

Small Bowel Series

LIQUID POLIBAR PLUS[®] can be used for small bowel series. It can be given alone or can be used following the completion of a double-contrast examination of the stomach using E-Z-HD[™]. It may be given either undiluted or in 1:1 dilution. Higher dilution will decrease the density of the barium sulfate but will increase the speed of the flow of contrast.

Typical Adult Dose: 340 mL to 750 mL of diluted or undiluted as applicable.

STORAGE

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

HOW SUPPLIED

LIQUID POLIBAR PLUS[®] is supplied as follows:
750 mL jugs, NDC 32909-167-55.

Rx Only

SHAKE WELL PRIOR TO USE

Manufactured by
 E-Z-EM Canada Inc.
 for E-Z-EM, Inc.
 a subsidiary of Bracco Diagnostics Inc.
 Monroe Township, NJ 08831
 Tel: 1-516-333-8230 1-800 544-4624
 rev. 02/20 CL10F901

Liquid Polibar Plus Bottle
 NDC:32909-167-55

750 mL NDC 32909-167-55

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BARIUM SULFATE SUSPENSION (105% w/v)

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 Monroe Twp., NJ 08831
 Tel: 1-516-333-8230
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 Manufactured in Canada

DOUBLE CONTRAST COLON STUDIES

For dosing and other prescribing information see product insert.

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

SHAKE WELL PRIOR TO USE

SIN 9228P rev. 02/20

CI10FA01

Lot Exp

(01)10332909167551

LIQUID POLIBAR PLUS

barium sulfate suspension

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:32909-167
Route of Administration	ORAL, RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
barium sulfate (UNII: 25BB7EKE2E) (barium sulfate - UNII:25BB7EKE2E)	barium sulfate	1.05 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
acacia (UNII: 5C5403N26O)	

anhydrous citric acid (UNII: XF417D3PSL)
dimethicone 350 (UNII: 2Y53S6ATLU)
dimethicone 1000 (UNII: MCU2324216)
hydrochloric acid (UNII: QTT17582CB)
polysorbate 80 (UNII: 6OZP39ZG8H)
potassium chloride (UNII: 660YQ98I10)
potassium sorbate (UNII: 1VPU26JZZ4)
water (UNII: 059QF0KOOR)
saccharin sodium (UNII: SB8ZUX40TY)
silicon dioxide (UNII: ETJ7Z6XBU4)
sodium benzoate (UNII: OJ245FE5EU)
carrageenan (UNII: 5C69YCD2YJ)
trisodium citrate dihydrate (UNII: B22547B95K)
sorbitol (UNII: 506T60A25R)
xanthan gum (UNII: TTV12P4NEE)

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:32909-167-55	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021	03/31/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		02/01/2021	03/31/2026

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

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

Establishment

Name	Address	ID/FEI	Business Operations
E-Z-EM Canada Inc		204211163	ANALYSIS(32909-167) , PACK(32909-167) , MANUFACTURE(32909-167) , LABEL(32909-167)