

E-Z-PAQUE

BARIUM SULFATE FOR SUSPENSION (96% w/w)

DESCRIPTION: E-Z-PAQUE is a barium sulfate for suspension (96% w/w) for oral administration. Each 100 g contains 96 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 alkalis, and organic solvents. Inactive Ingredients: artificial strawberry flavor, bentonite, citric acid, natural and artificial vanilla flavor, natural gums, polyoxyethylene glyceryl monooleate, propylene glycol, saccharin sodium, simethicone, sodium citrate, and sorbitol.

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 USAGES:

For use only in X-ray departments. Single-contrast radiography of the oesophagus, stomach duodenum and small bowel by oral administration (unit dose bottle presentation).

Radiographic visualization of the gastro-intestinal tract by oral or rectal (enema) administration (bulk pack presentation).

CONTRAINDICATIONS: This product should not be used in patients with known gastric or intestinal perforation or hypersensitivity to barium sulfate products and other ingredients of the product.

WARNINGS: Rarely, severe allergic reactions of an anaphylactoid nature, have been reported following administration of barium sulfate contrast agents. Appropriate facilities and trained personnel 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.

Use with caution in patients with complete or nearly complete obstruction of the GI tract.

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 for 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, 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. 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 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.

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:

The volume and concentration of E-Z-PAQUE 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.

Mixing Instructions – Unit Dose Bottle: Add water to the desired % w/w fill line on the bottle. Replace the lid, invert the bottle and tap with fingers to mix contrast with water. Shake vigorously for 30 seconds. Wait five minutes, then add more water as necessary to achieve the % w/w desired. Replace the lid and shake vigorously for 30 seconds.

Mixing Instructions – Bulk Presentation

Add one level scoop of the product (approximately 250 g) to a mixing container. Referring to the table below, fill the supplied graduated scoop with the appropriate amount of water, according to the desired final concentration.

*BaSO4 % w/w	*BaSO4 % w/v	Total water added (ml)	Final Volume (ml)	Route of administration
61	115	150	209	ORAL
50	83	230	289	ORAL
40	59	350	409	ORAL
20	24	950	1010	RECTAL
17	20	1150	1210	RECTAL
14	16	1450	1510	RECTAL

Transfer the water to the mixing container. Cover and invert the mixing container and tap with fingers to mix the contrast into the water. Shake the container vigorously for 30 seconds, wait 10 minutes, then re-shake thoroughly.

* Represents approximate concentration after reconstitution and mixing.

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

HOW SUPPLIED:

E-Z-PAQUE is supplied in the following quantities:
Bottle containing 177 g powder (unit dose presentation). Pail containing 10 kg powder (bulk presentation).

Manufactured by:

E-Z-EM Canada Inc.
a subsidiary of E-Z-EM, Inc.
Westbury, NY 11590

Registration Holder: Promedico Ltd., 4 Baltimore St. Petach-Tikva.

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