LIQUID POLIBAR PLUS® Barium Sulfate Suspension (105% w/v, 58% w/w)

INDICATION

LIQUID POLIBAR PLUS Barium Sulfate Suspension is indicated for radiography of the gastrointestinal tract.

IMPORTANT SAFETY INFORMATION

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 AND PRECAUTIONS:

Rarely, severe allergic reactions of an anaphylactoid nature have been reported. 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.

General

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 the integrity of the swallowing mechanism is unknown, proceed with caution. If this product is aspirated into the larynx, further administration should be immediately discontinued.

It is important to rehydrate the patient as quickly as possible to prevent the 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 patients 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.

Drug Interactions

The presence of barium sulfate formulations in the GI tract may alter the absorption of therapeutic agents taken concomitantly. Separate administration of barium sulfate from that of other agents to minimize potential absorption.

Pregnancy

Radiation is known to cause harm to the unborn fetus exposed in utero. Therefore, radiographic procedures should only be used when their use is deemed essential to the welfare of the pregnant patient.

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 and fatalities 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.

Because EKG changes have been reported following or during barium enema procedures it is important to be prepared to treat any such occurrence.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for full Prescribing Information for LIQUID POLIBAR PLUS® Barium Sulfate Suspension (105% w/v, 58% w/w).

LIQUID POLIBAR PLUS is manufactured by E-Z-EM Canada Inc., for E-Z-EM, Inc., a subsidiary of Bracco Diagnostics Inc., Monroe Twp., NJ 08831.

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