NeuLumEX[™] BARIUM SULFATE SUSPENSION (0.1% w/v)

INDICATION

NeuLumEX barium sulfate suspension is for use in Computed Tomography to opacify the gastrointestinal tract.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

This product should not be used in patients with known or suspected gastrointestinal perforation or hypersensitivity to barium sulfate or any component of this barium sulfate formulation.

WARNINGS AND PRECAUTIONS

Rare 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

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

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, granuloma formation, intravasation, embolization, and peritonitis following intestinal perforation, vasovagal and syncopal episodes, and fatalities.

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 <u>here</u> for full Prescribing Information for NeuLumEX[™] BARIUM SULFATE SUSPENSION (0.1% w/v).

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

NeuLumEX is a trademark of E-Z-EM, Inc.

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