GASTROGRAFIN® (Diatrizoate Meglumine and Diatrizoate Sodium Solution USP)

INDICATION

Gastrografin (Diatrizoate Meglumine and Diatrizoate Sodium Solution) is indicated for radiographic examination of segments of the gastrointestinal tract (esophagus, stomach, proximal small intestine, and colon). The preparation is particularly indicated when a more viscous agent such as barium sulfate, which is not water-soluble, is not feasible or is potentially dangerous.

Gastrografin may also be used as an adjunct to contrast enhancement in computed tomography of the torso (body imaging); the preparation is indicated, in conjunction with intravenous administration of a radiopaque contrast agent, when unenhanced imaging may not provide sufficient definition in distinguishing normal loops of bowel from adjacent organs or areas of suspected pathology.

CONTRAINDICATIONS

Do not administer to patients with a known hypersensitivity to Gastrografin or any of its components.

WARNINGS AND PRECAUTIONS

Dehydration: Administration of hypertonic Gastrografin solutions may lead to hypovolemia and hypotension due to fluid loss from the intestine. Less dilute solutions are hypertonic and may lead to intraluminal movement of fluid with resulting hypovolemia. In young or debilitated children and in elderly cachectic persons, the loss of plasma fluid may be sufficient to cause a shock-like state. If Gastrografin is used in infants and children (under 10 kg) or in dehydrated or debilitated patients, prepare the solution using the specific dilutions described in DOSAGE AND ADMINISTRATION. In debilitated patients and in patients with electrolyte imbalances, postprocedural monitoring of hydration, serum osmolarity, electrolytes, and clinical status is essential. In pediatric or severely debilitated patients, maintain an open intravenous fluid line for rehydration should hypotension or shock supervene. Correct electrolyte disturbances prior to any hypertonic Gastrografin solutions administration.

Aspiration: Aspiration of Gastrografin into the trachea and airways may result in serious pulmonary complications including, pulmonary edema, pneumonitis, or death. Bronchial entry of any orally administered contrast medium causes a copious osmotic effusion. Avoid the use of Gastrografin in patients with esophagotracheal fistula and minimize risks for pulmonary aspiration in all patients. If Gastrografin is given by nasogastric tube, verify the position of the tube in the stomach before administration.

Anaphylactic reactions: Anaphylactic reactions, including fatalities, have been reported. Patients with a history of a previous reaction to a contrast medium, known sensitivity to

iodine, and known clinical hypersensitivity (bronchial asthma, hay fever, and food allergies) are at increased risk. Medical personnel trained in the treatment of anaphylactic reactions, necessary drugs, and medical equipment should be readily available when Gastrografin is used.

Diagnostic procedures: using radiopaque contrast agents should be carried out under the direction of personnel with the prerequisite training and with a thorough knowledge of the particular procedure to be performed. Appropriate facilities should be available for coping with any complication of administration, as well as for treatment of reaction to the contrast medium.

Rectal administration: of undiluted Gastrografin in any patient, particularly with large doses and/or in those with overdistention, has been reported to be associated with mucosal irritation.

Hyperthyroidism: Cases of hyperthyroidism have been reported with the use of oral contrast media. Some patients had multinodular goiters which may have been responsible for the increased hormone synthesis in response to excess iodine. Administration of an intravascular iodinated radiopaque diagnostic agent to a hyperthyroid patient precipitated thyroid storm; a similar situation could follow the administration of oral preparations of iodides. Use caution when administering enteral gastrointestinal radiopaque agents to hyperthyroid and euthyroid goiterous patients.

Hyperacidity Conditions: The potential for precipitation of water-soluble contrast agents under conditions that may promote hyperacidity (i.e., fasting, emotional upset, or stress) should be considered. The possibility of interpreting the precipitate radiologically as an anatomical abnormality (i.e., ulceration of the stomach or small intestine) or injury, should be kept in mind.

ADVERSE REACTIONS

Most adverse reactions to enteral diagnostic radiopaque agents are mild and transitory. Nausea, vomiting and/or diarrhea, urticaria with erythema, hypoxia, acute dyspnea, tachyarrhythmia, and anaphylaxis have occurred following ingestion of the contrast medium, particularly when high concentrations of large volumes of solution are administered. Severe changes in serum osmolarity and electrolyte concentrations may produce shock-like states. It should be kept in mind that serious or anaphylactoid reactions that may occur with intravascular administration of radiopaque contrast agents are theoretically possible following administration by other routes.

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 Gastrografin® (Diatrizoate Meglumine and Diatrizoate Sodium Solution USP).

GASTROGRAFIN is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831 by E-Z-EM Canada Inc.

GASTROGRAFIN is a registered trademark of Bracco Diagnostics Inc.

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