



MD-Gastroview™ (diatrizoate meglumine and diatrizoate sodium solution USP)

This information is intended for U.S. Healthcare Professionals only.

For more than 25 years, clinicians have relied on MD-Gastroview contrast agent for radiographic examination of segments of the gastrointestinal tract, and as a bowel marker in CT. It is now available in a convenient 30 mL bottle.

MD-Gastroview contrast agent is water-soluble, ionic and high-osmolar, and is used for both oral and rectal radiographic examinations of segments of the gastrointestinal tract and as an adjunct to contrast enhancement in computed tomography (CT) of the body. It opacifies the gastrointestinal tract. MD-Gastroview contrast agent is palatable, ready to use, offers quick and accurate dosing, and accelerated transition time. It can be diluted and mixed with water, milk, carbonated beverages or mineral oil, and is particularly suited for times when a more viscous agent such as barium sulfate (not water soluble) is not feasible or is potentially dangerous. It is a prescription drug that is intended to be essentially therapeutically and biologically inert when ingested or administered rectally. Each milliliter contains 660 mg of diatrizoate meglumine and 100 mg of diatrizoate sodium. The solution contains approximately 4.8 mg (0.21 mEq) sodium and 367 milligrams organically bound iodine in each milliliter.

INDICATIONS AND USAGE

MD-Gastroview™ (diatrizoate meglumine and diatrizoate sodium solution USP) 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.

MD-Gastroview 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.

IMPORTANT RISK INFORMATION

NOT FOR INTRATHECAL USE

CONTRAINDICATIONS

MD-Gastroview is contraindicated in patients with a known hypersensitivity to MD-Gastroview or any of its components.

WARNINGS AND PRECAUTIONS

- Anaphylactic reactions, including fatalities, have been reported with the use of MD-Gastroview. Patients at increased risk include those with a history of a previous reaction to a contrast medium, patients with a known sensitivity to iodine, and patients with a known clinical hypersensitivity (bronchial asthma, hay fever, and food allergies). Medical personnel trained in the treatment of anaphylactic reactions and the necessary drugs and medical equipment should always be readily available when MD-Gastroview is used.

- Administration of hypertonic MD-Gastroview solutions may lead to hypovolemia and hypotension due to fluid loss from the intestine. In young or debilitated children and in elderly cachectic persons, the loss of plasma fluid may be sufficient to cause a shock-like state.
- Aspiration of MD-Gastroview into the trachea and airways may result in serious pulmonary complications including, pulmonary edema, pneumonitis or death.
- Cases of hyperthyroidism have been reported with the use of oral contrast media. Some of these patients reportedly 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 administration of oral preparations of iodides.
- Consideration should be given to the potential for precipitation of water-soluble contrast agents under conditions that may promote hyperacidity (i.e., fasting, emotional upset, or stress, laceration of the stomach or small intestine) although the incidence has not yet been reported.

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 or 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.

Use in Specific Populations

- In pediatric or severely debilitated patients, the maintenance of an open intravenous fluid line for rehydration may be advisable should hypotension or shock supervene.
- In pediatric patients local injury to the colonic mucosa, particularly in the presence of underlying disease which interferes with intestinal viability, has been reported in cases where recommended doses and dilutions
- Diatrizoate meglumine is excreted in breast milk following intravascular administration. Caution should be exercised when administered to a nursing woman

ORDERING INFORMATION

Description	Qty	Unit	Size	Order #	11 Digit NDC
Bottle	25	each	30mL	481604	00019481604