

MD-GASTROVIEW- diatrizoate meglumine and diatrizoate sodium solution
Mallinckrodt Inc.

September 2012

MD-Gastroview®

**[DIATRIZOATE MEGLUMINE AND
DIATRIZOATE SODIUM SOLUTION U.S.P.]**

Mallinckrodt Inc.

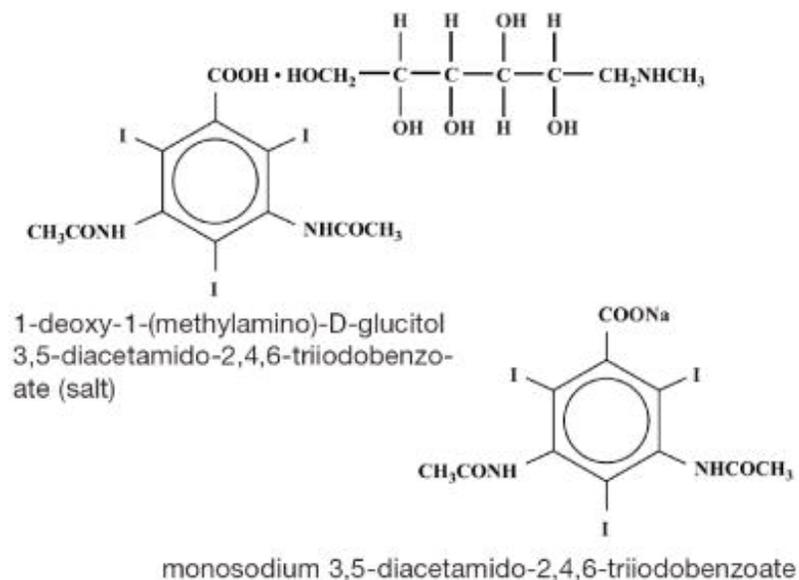
Rx Only

DESCRIPTION

MD-GASTROVIEW (Diatrizoate Meglumine and Diatrizoate Sodium Solution) is a palatable lemon-vanilla flavored water-soluble iodinated radiopaque contrast medium for oral or rectal administration only. Each mL contains 660 mg diatrizoate meglumine and 100 mg diatrizoate sodium; pH has been adjusted to 6.0 to 7.6 with sodium hydroxide. Each mL contains approximately 4.8 mg (0.21 mEq) sodium and 367 mg organically bound iodine. MD-GASTROVIEW does not contain the wetting agent polysorbate 80.

The inactive ingredients are: Edetate Disodium Dihydrate, Lemon-Vanilla Flavor, Sodium Citrate, Sodium Hydroxide, Sodium Saccharin, Water for Injection. Air in the container is displaced with nitrogen.

Diatrizoate meglumine is designated chemically as 1-deoxy-1-(methylamino)-D-glucitol 3,5-diacetamido-2,4,6-triiodobenzoate (salt); diatrizoate sodium is monosodium 3,5-diacetamido-2,4,6-triiodobenzoate. The two salts have the following structural formulae:



CLINICAL PHARMACOLOGY

The most important characteristic of contrast media is the iodine content. The relatively high atomic weight of iodine contributes sufficient radiodensity for radiographic contrast with surrounding tissues.

Diagnostic enteral radiopaque agents have few known pharmacological effects. Diatrizoate meglumine and diatrizoate sodium exert a mild laxative effect attributable to their high osmolality.

Diatrizoate meglumine and diatrizoate sodium are sparingly absorbed from the intact gastrointestinal tract, and therefore permit gastrointestinal opacification and delineation after oral or rectal administration. Oral administration is used for radiographic evaluation of the esophagus, stomach and proximal small intestine. Rectal administration is used for examination of the colon; however, visualization of the distal small bowel is generally unsatisfactory, since the hypertonicity of the medium causes intraluminal diffusion of water with subsequent dilution of the medium. Enough absorption from the gastrointestinal tract to permit incidental visualization of the urinary tract has been reported; this should also be considered when thyroid testing is being contemplated, since iodine-mediated thyrotropic effects may occur (see PRECAUTIONS).

INDICATIONS AND USAGE

MD-GASTROVIEW (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.

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.

CONTRAINDICATIONS

Do not administer to patients with a known hypersensitivity to MD-GASTROVIEW or any of its components.

WARNINGS

Dehydration: Administration of hypertonic MD-GASTROVIEW solutions may lead to hypovolemia and hypotension due to fluid loss from the intestine. A 1 in 4.6 (1:4.6) dilution of MD-GASTROVIEW yields an approximately isotonic 16.5 percent diatrizoate salts solution; 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 MD-GASTROVIEW is used in infants and children (under 10 kg) or in dehydrated or debilitated patients, the solution must be prepared using the specific dilutions described in DOSAGE AND ADMINISTRATION. In debilitated patients and in patients with electrolyte imbalances, postprocedural monitoring of hydration, serum osmolality, electrolytes and clinical status is essential. In pediatric or severely debilitated patients, the maintenance of an open intravenous fluid line for rehydration may be advisable should hypotension or shock supervene. Electrolyte disturbances must be corrected prior to the administration of any hypertonic MD-GASTROVIEW solutions.

Aspiration: Aspiration of MD-GASTROVIEW 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. Therefore, avoid use of MD-GASTROVIEW in patients with esophagotracheal fistula and minimize risks for pulmonary aspiration in all patients. If MD-GASTROVIEW is given by nasogastric tube, the position of the tube in the stomach must be verified before administration.

Anaphylactic Reactions: 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.

PRECAUTIONS

General

Diagnostic procedures which involve the use of 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 (see ADVERSE REACTIONS, and PRECAUTIONS, Information for the Patient).

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

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. Therefore, caution should be exercised when administering enteral gastrointestinal radiopaque agents to hyperthyroid and euthyroid goiterous patients.

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). Harmful effects directly attributable to precipitate formation have not been reported. However, 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.

Information for the Patient

Patients should receive the following information and instructions:

1. This drug has been prescribed to perform an X-ray of the gastrointestinal tract.
2. Inform the physician if pregnant or if allergic to iodine, any foods, or X-ray materials.
3. The iodine in diatrizoate salts may interfere with some thyroid tests if these are needed in the future. Inform the attending physician at that time about this gastrointestinal study.
4. This drug may cause abdominal cramping, nausea, vomiting, diarrhea, skin rashes, itching, heartburn, dizziness, or headache in some patients, but most reactions are mild and pass quickly.

Drug/Laboratory Test Interactions

Thyroid Function Tests

The results of protein bound iodine (PBI) and radioactive iodine uptake studies, which depend on iodine estimations, will not accurately reflect thyroid function for six months, and possibly as long as one year, following the administration of diagnostic enteral radiopaque media.

Thyroid function tests, if indicated, generally should be performed prior to the administration of any iodinated agent. However, thyroid function can be evaluated after use of these agents by using T₃ resin uptake and total or free thyroxine (T₄) assays, which are not dependent on iodine estimations.

Pancreatic Tests

Small quantities of contrast medium in the intestinal tract may cause false low trypsin values when determined spectrophotometrically. Therefore, duodenal instillation should not precede pancreatic

function tests involving spectrophotometric trypsin assays.

Any test which might be affected by contrast media should be performed prior to administration of the contrast medium.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic or mutagenic potential, or possible impairment of fertility in males or females.

Pregnancy Category B

When administered intravenously, diatrizoate salts cross the placenta and are evenly distributed in fetal tissues.

No teratogenic effects attributable to diatrizoate meglumine or diatrizoate sodium have been observed in teratology studies performed in animals. There are, however, no adequate and well-controlled studies in pregnant women. Because small amounts of these agents may be absorbed, and animal teratology studies are not always predictive of human response, these agents should be used during pregnancy only when clearly needed.

Procedures including radiation involve a certain risk related to the exposure of the fetus.

Nursing Mothers

Diatrizoate meglumine is excreted in breast milk following intravascular administration.

Because small amounts of enteral gastrointestinal radiopaque agents may be absorbed following oral or rectal administration, caution should be exercised when they are administered to a nursing woman.

Pediatric Use

See WARNINGS, and PRECAUTIONS, General.

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 (see DOSAGE AND ADMINISTRATION) were not used.

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 (see WARNINGS). 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.

OVERDOSAGE

See WARNINGS regarding potential hypovolemia, hypotension, or shock. The maintenance of an open intravenous fluid line for rehydration may be advisable. See DOSAGE AND ADMINISTRATION for appropriate doses and dilutions. Treatment of an overdose should be directed toward the support of all vital functions, and prompt institution of symptomatic therapy.

DOSAGE AND ADMINISTRATION

General

This medium is not to be used for the preparation of solutions for parenteral administration. Oral or rectal use only.

The routine preparatory measures employed for barium studies are also appropriate for this agent. For pediatric and severely cachectic patients, the maintenance of an intravenous fluid line may be advisable.

Radiographic Examination of Segments of the Gastrointestinal Tract

Oral Administration: Adult oral dosage may range from 30 to 90 mL (11 to 33 g iodine), depending on the nature of the examination and the size of the patient. For infants and children less than 5 years of age, 30 mL (11 g iodine) are usually adequate; for children 5 to 10 years of age, the suggested dose is 60 mL (22 g iodine). These pediatric doses may be diluted 1:1, if desired, with water, carbonated beverage, milk, or mineral oil. When used in infants, the solution may be given in a nursing bottle. Pediatric doses may also be used in dehydrated and/or debilitated adult patients. A 1:1 dilution is also recommended when the contrast medium is used in elderly cachectic individuals.

For very young (under 10 kg) and debilitated children *the dose should be diluted:* 1 part MD-GASTROVIEW (Diatrizoate Meglumine and Diatrizoate Sodium Solution) in 3 parts water is recommended.

For Enemas or Enterostomy Instillations: MD-GASTROVIEW should be diluted when it is used for enemas and enterostomy instillations.

When used as an enema, the suggested dilution for adults is 240 mL (88 g iodine) in 1,000 mL of tap water. For children under 5 years of age, a 1:5 dilution in tap water is suggested; for children over 5 years of age, 90 mL (33 g iodine) in 500 mL of tap water is a suitable dilution.

Tomography (Body Imaging)

A usual adult dose is 240 mL of a dilute MD-GASTROVIEW solution prepared by diluting 25 mL (9.17 g iodine) to one liter with tap water. Less dilute solutions [up to 77 mL (28.26 g iodine) diluted to one liter with tap water] may be used when indicated. The dose is administered orally about 15 to 30 minutes prior to imaging in order to permit the contrast medium to reach the pelvic loops.

HOW SUPPLIED

Available as an aqueous lemon-vanilla flavored solution in bottles of 30 mL in packages of 25 (NDC 0019-4816-04).

Storage

Protect from light. Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]; Avoid excessive heat. If precipitation or solidification has occurred due to storage in the cold, the bottle should be brought to room temperature. Shake intermittently to redissolve any solids.

As with all contrast media, containers should be inspected prior to use to ensure that breakage or other damage has not occurred during shipping and handling. All containers should be inspected for closure integrity. Damaged containers should not be used.

MD-Gastroview is a registered trademark of Mallinckrodt Inc.

tyco / Healthcare
Mallinckrodt

Mallinckrodt Inc.
St. Louis, MO 63042 USA
www.Mallinckrodt.com

MKR 48160912

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Printed in U.S.A.

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - Case Label

MD-Gastroview®

DIATRIZOATE MEGLUMINE AND DIATRIZOATE SODIUM SOLUTION U.S.P.

37% Organically Bound Iodine For Gastrointestinal Radiography

Not For Parenteral Use

Rx Only

11040809

MD-Gastroview® 4816UD

**DIATRIZOATE MEGLUMINE
AND DIATRIZOATE
SODIUM SOLUTION U.S.P.**

37% Organically Bound Iodine
For Gastrointestinal Radiography

Not For Parenteral Use

Rx Only

11040809

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature];
Avoid excessive heat.

**Single-Unit Container • Dilute Before Use
Discard unused portion • Protect from light**

Usual Dosage: See Package Insert. Dispense in Tight, Light Resistant
Containers. Oral or rectal use only.

Each mL contains 660 mg diatrizoate meglumine and 100 mg diatrizoate
sodium. Each 30 mL contains approximately 11 grams organically bound
iodine, pH adjusted to 6 to 7.6 with sodium hydroxide. Inactive
ingredients: Edetate Disodium Dihydrate, Lemon-Vanilla Flavor, Sodium
Citrate, Sodium Hydroxide, Sodium Saccharin, Water for Injection.

Mallinckrodt Inc.
St. Louis, MO 63042 USA **tyco** Healthcare **MALLINCKRODT**
www.Mallinckrodt.com

MD-GASTROVIEW

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Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:0019-4816
Route of Administration	ORAL, RECTAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIATRIZOATE MEGLUMINE (DIATRIZOIC ACID)	DIATRIZOATE MEGLUMINE	600 mg in 1 mL
DIATRIZOATE SODIUM (DIATRIZOIC ACID)	DIATRIZOATE SODIUM	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM	
GLYCINE	
SODIUM CITRATE	
SODIUM HYDROXIDE	
SACCHARIN SODIUM	
WATER	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON, VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0019-4816-04	25 in 1 BOX		
1		30 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA087388	08/31/2009	

Labeler - Mallinckrodt Inc. (047021092)

Establishment			
Name	Address	ID/FEI	Business Operations
JUSTESA IMAGEN SA		477020325	API MANUFACTURE(00 19-48 16)

Establishment			
Name	Address	ID/FEI	Business Operations
Mallinckrodt Inc.		109024984	ANALYSIS(00 19-48 16), MANUFACTURE(00 19-48 16)

Revised: 9/2012

Mallinckrodt Inc.