**Gastrografin (Diatrizoate Meglumine and Diatrizoate Sodium Solution USP)**

**DESCRIPTION**

Gastrografin (Diatrizoate Meglumine and Diatrizoate Sodium Solution) is a palatable lemon-flavored water-soluble iodinated radiopaque contrast medium for oral or rectal administration only. Each mL contains approximately 4.8 mg (0.21 meq) sodium and 367 mg organically bound iodine. Inactive ingredients: edetate disodium, flavor, polysorbate 80, purified water, saccharin sodium, simethicone, and sodium citrate.

Diatrizoate meglumine is designated chemically as 1-deoxy-1-(methylamino)-3,5-diaceamido-2,4,6-triiodobenzoate (salt); diatrizoate sodium is 1-deoxy-1-(methylamino)-3,5-diaceamido-2,4,6-triiodobenzoate (salt); diatrizoate meglumine is designated chemically as 1-deoxy-1-(methylamino)-3,5-diaceamido-2,4,6-triiodo-6-triiodobenzoate.

**Stoichiometric Formulas:**

- **Diatrizoate meglumine:**
  \( C_{11}H_9I_3N_2O_4 \)
  MW 809.13
  Organically Bound Iodine: 47.1%
  CAS-131-49-7

- **Diatrizoate sodium:**
  \( C_{11}H_8I_3N_2NaO_4 \)
  MW 635.90
  Organically Bound Iodine: 59.9%
  CAS-737-31-5

**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 pharmacological effects. Diatrizoate meglumine and diatrizoate sodium exert a mild laxative effect attributable to their high osmolarity. Small quantities of contrast medium causes a copious osmotic diarrhea, 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 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 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 particularly indicated when a more viscous agent such as barium sulfate, which is not water-soluble, is not feasible or is potentially dangerous.

**CONTRAINDICATIONS**

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

**WARNINGS**

Dehydration: Administration of hypertonic Gastrografin may lead to hypovolemia and hypotension due to fluid loss from the intestine. A 1:4:6 (1:4:6) dilution of Gastrografin yields an approximately isotonic iodine solution; less dilute solutions are hypertonic and may lead to intraluminal movement of fluid with resulting hypovolemia. In young or debilitated children or elderly 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, 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, electrolyte, and hematocrit should be performed. 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 Gastrografin solution.

**INDICATIONS AND USAGE**

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 particularly indicated when a more viscous agent such as barium sulfate, which is not water-soluble, is not feasible or is potentially dangerous.

**RECOMMENDATIONS**

Cases of hyperthyroidism have been reported with the use of Gastrografin. 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 history of hyperthyroidism (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 Gastrografin 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 requisite 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 Gastrografin (Diatrizoate Meglumine and Diatrizoate Sodium Solution) may cause hyperventilation, particularly with large doses and/or in those with overdistention, has been reported to be associated with mucusal irritation.

**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.

**Pancreatic Tests**

Small quantities of contrast medium administered orally may have been reported with the use of oral contrast media. Some of these patients reportedly had abdominal pain or nausea which may have been responsible for the increases in 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 in the administration of iodinated radiopaque agents to hyperthyroid and euthyroid goitrous patients.

**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 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 and the normal loops of bowel from adjacent organs or areas of suspected pathology.

**ADVERSE REACTIONS**

Skin: rash, urticaria, pruritus, angioedema, flushing, 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 Gastrografin is used.
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**

When administered intravenously, diatrizoate salts cross the placenta and are evenly distributed in fetal tissues. 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; when extemporaneous dosage is elected, the polysorbate 80 level in the dose may be a contributing factor to injury.

**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 (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 administration only. Discard any unused portion after procedure.

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 80 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 Gastrografin (Diatrizoate Meglumine and Diatrizoate Sodium Solution) in 3 parts of fluid line may be advisable. See USP; avoid excessive heat.

**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 Gastrografin 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**

Gastrografin (Diatrizoate Meglumine and Diatrizoate Sodium Solution USP) is available in packages of:

- Twenty-four 30 mL single dose bottles (NDC 0270-0445-35).
- Twelve 120 mL single dose bottles (NDC 0270-0445-40).

**Storage**

Protect from light. Store at 20-25°C (68-77°F) [See USP]; avoid excessive heat.

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**Rx only**

Manufactured by

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