PRESCRIBING INFORMATION

HYPAQUE ORAL POWDER
(Diatrizoate Sodium)

Contrast Medium

GE Healthcare Canada Inc.
2300 Meadowvale Blvd.
Mississauga, ON
L5N 5P9

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Control # 104484

HYPAQUE ORAL
(Diatrizoate Sodium)

CONTRAST MEDIUM

INDICATIONS: Radiography of gastrointestinal tract following oral or rectal administration.

PRECAUTIONS: Not for parenteral injection. Do not use for myelography. It is advisable to correct any electrolyte disturbances before using solutions that are extremely hypertonic. Caution is advised in patients with severe renal or hepatic disease, known hypersensitivity to diatrizoic acid compounds or hyperthyroidism.
Pregnancy: The safety of orally administered diatrizoate sodium solutions during pregnancy has not been established. Therefore, before administration of the drug to women of childbearing potential, the benefit to the patient should be carefully weighed against the possible risk to the fetus. In addition, most authorities consider elective contrast radiography of the abdomen contraindicated during pregnancy.
Lactation: Diatrizoate sodium administered intravascularly has been found to be excreted in breast milk.
Because small amounts may be absorbed from oral administration, caution should be exercised when diatrizoate sodium solutions are administered to a nursing woman.
Children: Solutions of diatrizoate sodium employed clinically are hypertonic, which may lead to intraluminal movement of fluid and may lead to hypovolemia. In infants and young children (under 10 kg), the loss of plasma fluid may be sufficient to cause a shock-like state; therefore, low concentrations (achieved by further dilution) must be used.
Diatrizoate sodium may be preferred over the diatrizoate meglumine/diatrizoate sodium combination, since the wetting agent (Tween 80) in the latter preparation may be injurious to the colonic mucosa.
Drug/Laboratory Test Interactions: Thyroid Function Tests: The results of protein bound iodine (PBI) and radioactive iodine uptake studies will not reliably reflect thyroid function for 6 months, and possibly as long as I 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 T_3 resin uptake or free thyroxin assays.
Pancreatic Test: Small quantities of diatrizoate sodium solution in the intestinal tract may cause falsely low spectrophotometrically determined trypsin values. Therefore, duodenal instillation of diatrizoate sodium should not precede pancreatic function tests involving spectrophotometric trypsin assays.

ADVERSE EFFECTS: The medium is slightly cathartic. With higher dosages urticaria, nausea, vomiting or diarrhea may be seen. Highly hypertonic solutions of the medium may draw excessive amounts of fluid into the intestine leading to the possibility of

hypovolemia and electrolyte imbalance especially in infants, debilitated patients, and those who are initially dehydrated.

DOSAGE: Adults: Orally: 90 to 180 mL of a 25 to 40% solution; Enema: 500 to 1000 mL of a 15 mL to 25% solution. Infants and children: Orally: 30 to 75 mL of a 20 to 40% solution; Enema: 100 to 500 mL of a 10 to 15% solution, depending on the weight of the patient.

Directions for Making Solutions from Hypaque Powder

Solution (%) approx.	Measuring spoons[a] of powder (Per 100mL diluent[b])
10	1
15	1½
20	2
25	2½
40	4

[a]One level measuring spoon is equal to approximately 10 g of powder.
[b]Solutions may be sweetened or flavored (e.g., with vanilla, lemon, chocolate); the diluent may be water, milk, or a carbonated drink. Carbonated diluents should be avoided when gas artifacts are undesirable.

The resulting solution should be used upon preparation; do not store for future use.

Supplied: Each g of calorie-free powder contains: diatrizoate sodium with iodine 59.87%. Nonmedicinal ingredients: caramel as coloring agent and 0.1% polysorbate 80. Gluten-, lactose-, starch-, suifite-, sucrose- and tartrazine-free. Containers of 250 g.