GADOTERATE MEGLUMINE

INJECTION, USP

To most, "generics" means bland, ordinary, and uninteresting. To us, it means the opportunity to be remarkable.

MAKING
GENERICS
REMARKABLE

PRODUCT DETAILS

- Concentration:
  2.5 mmol / 5 mL 5 mmol / 10 mL
  7.5 mmol / 15 mL 10 mmol / 20 mL
  50 mmol / 100 mL (Bulk Package)
- Fill volume:
  Sterile Solution in a
  5 mL, 10 mL, 15 mL, 20 mL vial
  Bulk Package of 100 mL vials
- Therapeutic Class:
  Contrast Agent
- Closure does not contain any natural rubber or latex.
- Preservative Free

NDC Numbers:

2.5 mmol / 5 mL | Box of 10 vials: 70436-123-31
5 mmol / 10 mL | Box of 10 vials: 70436-123-33
7.5 mmol / 15 mL | Box of 10 vials: 70436-123-34
10 mmol / 20 mL | Box of 10 vials: 70436-123-35
50 mmol / 100 mL | Box of 6 vials: 70436-123-56

To place an order or learn more,
call **888-447-0095 (Toll Free)**
or email **sales@slaterunpharma.com**
6am – 7pm CST (Monday - Friday)

Available through your wholesaler:

NDC: 70436-123-31
Cardinal Health: 5959416
McKesson: 3004520
Amerisource: 10295496

NDC: 70436-123-33
Cardinal Health: 5959382
McKesson: 3004538
Amerisource: 10295528

NDC: 70436-123-34
Cardinal Health: 5959390
McKesson: 3004546
Amerisource: 10295530

NDC: 70436-123-35
Cardinal Health: 5959408
McKesson: 3004553
Amerisource: 10295506

NDC: 70436-123-56
Cardinal Health: 5959374
McKesson: 3004959
Amerisource: 10295816

IMPORTANT SAFETY INFORMATION FOR:

GADOTERATE MEGLUMINE INJECTION, USP

WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS

Risk Associated with Intrathecal Use

Intrathecal administration of gadolinium-based contrast agents (GBCAs) can cause serious adverse reactions including death, coma, encephalopathy, and seizures. Gadoterate Meglumine Injection is not approved for intrathecal use.

Nephrogenic Systemic Fibrosis

GBCAs increase the risk for nephrogenic systemic fibrosis (NSF) among patients with impaired elimination of the drugs. Avoid use of Gadoterate Meglumine Injection in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.

The risk for NSF appears highest among patients with:

- **Chronic, severe kidney disease (GFR < 30 mL/min/1.73 m 2), or**
- **Acute kidney injury.**

Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (e.g. age > 60 years, hypertension, diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.

For patients at highest risk for NSF, do not exceed the recommended Gadoterate Meglumine Injection dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

Gadoterate Meglumine Injection is contraindicated in patients with history of clinically important hypersensitivity reactions to Gadoterate Meglumine Injection.

Anaphylactic and anaphylactoid reactions have been reported with Gadoterate Meglumine Injection, involving cardiovascular, respiratory, and/or cutaneous manifestations. Some patients experienced circulatory collapse and died. In most cases, initial symptoms occurred within minutes of Gadoterate Meglumine Injection administration and resolved with prompt emergency treatment. Before Gadoterate Meglumine Injection administration, assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders. These patients may have an increased risk for a hypersensitivity reaction to Gadoterate Meglumine Injection. Administer Gadoterate Meglumine Injection only in situations where trained personnel and therapies are promptly available for the treatment of hypersensitivity reactions, including personnel trained in resuscitation. During and following Gadoterate Meglumine Injection administration, observe patients for signs and symptoms of hypersensitivity reactions.

Gadolinium is retained for months or years in several organs. While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant and pediatric patients, and patients with inflammatory conditions. Consider the retention characteristics of the agent when choosing a GBCA for these patients. Minimize repetitive GBCA imaging studies, particularly closely spaced studies when possible.

The most frequent (≥ 0.2%) adverse reactions in clinical studies were nausea, headache, injection site pain, injection site coldness, and rash.

Please see the package insert for Gadoterate Meglumine Injection for full prescribing information.