GADOBUTROL
INJECTION

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

MAKING
GENERICS
REMARKABLE

PRODUCT DETAILS

- Concentration:
  7.5 mmol / 7.5 mmol
  15 mmol / 15 mmol
- Fill Volume:
  Sterile Solution in a
  7.5 mL vial (7.5 mmol)
  or 15 mL vial (15 mmol)
- Therapeutic Class: Contrast Agent
- Closure does not contain any natural rubber or latex.
- Preservative Free

NDC Numbers:

7.5 mmol | Box of 1 vial:
70436-212-80

7.5 mmol | Box of 20 vials:
70436-212-54

15 mmol | Box of 1 vial:
70436-214-80

15 mmol | Box of 20 vials:
70436-214-54

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: 70436-212-80
Cardinal Health: 5908496
McKesson: 2919793
Amerisource: 10287537

NDC: 70436-212-54
Cardinal Health: 5908504
McKesson: 2919892
Amerisource: 10287497

NDC: 70436-214-80
Cardinal Health: 5908512
McKesson: 2919868
Amerisource: 10287459

NDC: 70436-214-54
Cardinal Health: 5908520
McKesson: 2919926
Amerisource: 50005963

IMPORTANT SAFETY INFORMATION FOR:

GADOBUTROL INJECTION

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. Gadobutrol 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 gadobutrol 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/1.73m 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 (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.

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

Gadobutrol Injection is contraindicated in patients with history of severe hypersensitivity reactions to gadobutrol injection.

Anaphylactic and other hypersensitivity reactions with cardiovascular, respiratory or cutaneous manifestations, ranging from mild to severe, including death, have uncommonly occurred following gadobutrol injection administration. Before gadobutrol 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 gadobutrol injection. Administer gadobutrol injection only in situations where trained personnel and therapies are promptly available for the treatment of hypersensitivity reactions, including personnel trained in resuscitation.

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.

In patients with chronic renal impairment, acute kidney injury sometimes requiring dialysis has been observed with the use of some GBCAs. Do not exceed the recommended dose; the risk of acute kidney injury may increase with higher than recommended doses.

Most common adverse reactions (incidence ≥0.5%) are headache, nausea, and dizziness.

Please see the package insert for Gadobutrol Injection for full prescribing information.