SLATE RUN
PHARMACEUTICALS

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GENERICIMAGINGPRODUCTS.COM

GADOTERIDOL

INJECTION, USP

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

MAKING
GENERICS
REMARKABLE

PRODUCT DETAILS

- RLD: PROHANCE®
- Concentration:
  1.3965 g per 5 mL (279.3 mg/mL)
  2.793 g per 10 mL (279.3 mg/mL)
  4.1895 g per 15 mL (279.3 mg/mL)
  5.586 g per 20 mL (279.3 mg/mL)
- Fill Volume:
  Sterile Solution in a
  5 mL, 10 mL, 15 mL, or 20 mL vial
- Therapeutic Class: Contrast Agent
- Closure does not contain any natural rubber or latex.
- Preservative Free

NDC Numbers:

1.3965 g per 5 mL | Box of 5 vials: 70436-121-31
2.793 g per 10 mL | Box of 5 vials: 70436-121-33
4.1895 g per 15 mL | Box of 5 vials: 70436-121-34
5.586 g per 20 mL | Box of 5 vials: 70436-121-35

See reverse side for important safety information.

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: 70436-121-31
FFF: GAD012131
Cardinal Health: 5986724
McKesson: 3033073
Amerisource: 10299950

NDC: 70436-121-33
FFF: GAD012133
Cardinal Health: 5986732
McKesson: 3033081
Amerisource: 10299847

NDC: 70436-121-34
FFF: GAD012134
Cardinal Health: 5986740
McKesson: 3033123
Amerisource: 10300295

NDC: 70436-121-35
FFF: GAD012135
Cardinal Health: 5986757
McKesson: 3033131
Amerisource: 10300296

IMPORTANT SAFETY INFORMATION FOR:

GADOTERIDOL 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. Gadoteridol 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 Gadoteridol 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 greater than 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 gadoteridol dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

Gadoteridol Injection is contraindicated in patients with known allergy or hypersensitivity reactions to Gadoteridol Injection.

Anaphylactic and anaphylactoid reactions have been reported, involving cardiovascular, respiratory and/or cutaneous manifestations. Some patients experienced circulatory collapse and died. In most cases, initial symptoms occurred within minutes of gadoteridol administration and resolved with prompt emergency treatment. Prior to gadoteridol administration, ensure the availability of trained personnel and medications to treat hypersensitivity reactions. Consider the risk for hypersensitivity reactions, especially in patients with a history of hypersensitivity reactions or a history of asthma or other allergic disorders.

Gadolinium is retained for months or years in several organs. The highest concentrations have been identified in the bone, followed by other organs (e.g. brain, skin, kidney, liver, and spleen). 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 chronically reduced renal function, acute kidney injury requiring dialysis has occurred with the use of GBCAs. The risk of acute kidney injury may increase with increasing dose of the contrast agent; administer the lowest dose necessary for adequate imaging.

The most commonly reported adverse reactions are nausea and taste perversion with an incidence ≥ 0.9%.

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