ProHance®

(Gadoteridol) Injection, 279.3 mg/mL

STABILITY. SAFETY. EFFICACY.

MR Suite

Important Safety Information

ProHance® (Gadoteridol) Injection, 279.3 mg/mL

Indications and Usage:

CENTRAL NERVOUS SYSTEM

ProHance (Gadoteridol) Injection, 279.3 mg/mL is indicated for use in MRI in adults and children over 2 years of age to visualize lesions with abnormal vascularity in the brain (intracranial lesions), spine and associated tissues.

EXTRACRANIAL/EXTRASPINAL TISSUES

ProHance (Gadoteridol) Injection, 279.3 mg/mL is indicated for use in MRI in adults to visualize lesions in the head and neck.

IMPORTANT SAFETY INFORMATION:

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs 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 systemic 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/1.73m2), 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 or diabetes), estimate the glomerular fi iltrationrate (GFR) through laboratory testing.
- For patients at highest risk for NSF do not exceed the recommended ProHance dose and allow a sufficient period of time for elimination of the drug from the body prior to re-administration (see **WARNINGS**).

As with all paramagnetic agents, caution should be exercised in patients with deoxygenated sickle erythrocytes and renal insufficiency with or without hepatic impairment. The possibility of a reaction, including serious, life threatening, or fatal, anaphylactic or cardiovascular reactions, or other idiosyncratic reactions, should always be considered, especially in those patients with a history of a known clinical hypersensitivity or a history of asthma or other allergic disorders. Trace amounts of gadolinium may remain for months or years in body organs including bone (highest concentration), brain, liverspleen, kidneys and skin. Consequences of gadolinium retention in the brain have not been established. Pathologic and clinical consequences of retention in skin and other organs have been established in patients with impaired renal function. Minimize repetitive GBCA imaging studies, particularly close spaced studies when possible…

Please see booth representative for full Prescribing Information and Patient Medication Guide for additional important safety information for/regarding ProHance (Gadoteridol) Injection, 279.3 mg/mL at https://imaging.bracco.com/us-en/products/magnetic-resonance-imaging/prohance.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit https://www.fda.gov/Safety/MedWatch/default.htm or call 1-800-FDA-1088.

ProHance is manufactured for Bracco Diagnostics Inc. by BIPSO GmbH – 78224 Singen (Germany).

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