ISI FOR OMNISCAN™

IMPORTANT SAFETY INFORMATION ABOUT OMNISCAN™ (GADODIAMIDE)

PRODUCT INDICATIONS AND USE:

OMNISCAN is a gadolinium-based contrast agent for diagnostic magnetic resonance imaging (MRI) indicated for intravenous use to:

- Visualize lesions with abnormal vascularity in the brain, spine, and associated tissues
- Facilitate the visualization of lesions with abnormal vascularity within the thoracic, abdominal, pelvic cavities, and the retroperitoneal space

WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS

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

• GBCAs increase the risk for nephrogenic systemic fibrosis among patients with impaired elimination of the drugs. Avoid use of OMNISCAN in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. Do not administer OMNISCAN to 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 (e.g., age > 60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.

CONTRAINDICATIONS

- Patients with chronic, severe kidney disease (GFR < 30 mL/min/1.73m^2) or acute kidney injury
- Patients with prior hypersensitivity to OMNISCAN

WARNINGS AND PRECAUTIONS

- *Intrathecal administration of GBCAs* can cause serious adverse reactions including death, coma, encephalopathy, and seizures. The safety and effectiveness of OMNISCAN have not been established with intrathecal use. OMNISCAN is not approved for intrathecal use
- *GBCAs increase the risk for nephrogenic systemic fibrosis (NSF*) among patients with impaired elimination of the drugs. Avoid use of OMNISCAN among these patients unless the diagnostic information is essential and not available with non-contrast enhanced MRI or other modalities.
- *Anaphylactoid and other serious hypersensitivity reactions* including fatal reactions have occurred particularly in patients with history of allergy or drug reactions. Monitor patients closely for need of emergency cardiorespiratory support
- *Gadolinium is retained* for months or years in brain, bone, and other organs
- *Acute renal failure has* occurred in patients with preexisting renal insufficiency. Use the lowest necessary dose of OMNISCAN and evaluate renal function in these patients

ADVERSE REACTIONS

- The most frequent adverse reactions (≤ 3%) observed during OMNISCAN adult clinical studies were nausea, headache, and dizziness.
- Serious or life-threatening reactions include: cardiac failure, arrhythmia and myocardial infarction

USE IN SPECIFIC POPULATIONS

Pregnancy: Use only if imaging is essential during pregnancy and cannot be delayed

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 1-800-654-0118 or by email at gpv.drugsafety@gehealthcare.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Omniscan full Prescribing Information, including the Medication Guide, for additional important safety information.