OMNISCAN Important Safety Information

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. OMNISCAN 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 OMNISCAN 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.

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.

Do not exceed the recommended OMNISCAN dose and allow a sufficient period of time for elimination of the drug from the body prior to any readministration.

Indications

CNS (Central Nervous System): OMNISCAN is a gadolinium-based contrast agent indicated for intravenous use in MRI to visualize lesions with abnormal vascularity (or those thought to cause abnormalities in the blood-brain barrier) in the brain (intracranial lesions), spine, and associated tissues.

Body (Intrathoracic [noncardiac], Intra-abdominal, Pelvic and Retroperitoneal Regions): OMNISCAN is a gadolinium-based contrast agent indicated for intravenous use in MRI to facilitate the visualization of lesions with abnormal vascularity within the thoracic (noncardiac), abdominal, pelvic cavities, and the retroperitoneal space.

Important Safety Information

OMNISCAN is contraindicated in patients with chronic, severe kidney disease (glomerular filtration rate, GFR < 30 mL/min/1.73m^2) or acute kidney injury and/or prior hypersensitivity to OMNISCAN.

Risk Associated with Intrathecal Use: 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.

Nephrogenic Systemic Fibrosis: 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. The GBCA-associated NSF risk appears highest for patients with chronic, severe kidney disease as well as patients with acute kidney injury. Do not administer OMNISCAN to these patients. Screen patients for acute kidney injury and other conditions that may reduce renal function. Do not exceed the recommended dose.

Hypersensitivity Reactions: Anaphylactoid and anaphylactic reactions, with cardiovascular, respiratory and/or cutaneous manifestations, resulting in death have occurred. Trained personnel and resuscitation equipment should be present prior to administration. Stop OMNISCAN if hypersensitivity reactions occur. Closely monitor patients with a history of drug reactions, asthma, allergies and hypersensitivity disorders.

Gadolinium Retention: Gadolinium is retained for months or years in several organs; especially bone and other organs. Consequences of gadolinium retention in the brain have not been established. Pathologic and clinical consequences of GBCA administration and retention in skin and other organs have been established in patients with impaired renal function.

Acute Renal Failure: In patients with renal insufficiency, acute renal failure requiring dialysis or worsening renal function have occurred, mostly within 48 hours of OMNISCAN Injection. The risk of renal failure may increase with increasing dose of gadolinium contrast. Use the lowest necessary.

Impaired Visualization of Lesions Detectable with non-contrast MRI: Paramagnetic contrast agents such as OMNISCAN might impair the visualization of lesions which are seen on the non-contrast MRI. Exercise caution when OMNISCAN MRI scans are interpreted in the absence of a companion non-contrast MRI.

Laboratory Test Findings: Asymptomatic, transitory changes in serum iron have been observed. The clinical significance is unknown. In patients with decreased renal function, the interference with calcium measurements is expected to last during the prolonged elimination of OMNISCAN. After patients receive OMNISCAN, careful attention should be used in selecting the type of method used to measure calcium.

Adverse Reactions: The most frequent adverse reactions were nausea, headache, and dizziness that occurred in 3% or less of the patients. Postmarketing experience reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: acute pancreatitis with onset within 48 hours after GCBA administration. *Please see full prescribing information for a complete list of adverse reactions including postmarketing events.*

Pregnancy: GBCAs cross the human placenta and result in fetal exposure and gadolinium retention. The human data on the association between GBCAs and adverse fetal outcomes are limited and inconclusive.

Prior to Omniscan administration, please read the [*full Prescribing Information need insert link***] for additional Important Safety Information.**

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2 then option 1) or by email at GPV.drugsafety@gehealthcare.com or FDA at 800 FDA 1088 or www.fda.gov/medwatch