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Gadoterate Meglumine for Use with Magnetic Resonance Imaging (Dotarem)

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]. NSF has not been reported in patients with a clear history of exposure to **WARNINGS AND PRECAUTIONS**GBCAs have been associated with a risk for NSF [see DOTAREM alone.

].**WARNINGS AND PRECAUTIONS** Hypersensitivity reactions and acute kidney injury are described in other sections of the labeling [see

Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The data described below reflect DOTAREM exposure in 2813 patients, representing 2672 adults and 141 pediatric patients. Overall, 55% of the patients were men. In clinical trials where ethnicity was recorded the ethnic distribution was 74% Caucasian, 12% Asian, 4% Black, and 10% others. The average age was 53 years (range from 0.1 to 97 years).

Overall, 3.9% of patients reported at least one adverse reaction, primarily occurring immediately or several days following DOTAREM administration. Most adverse reactions were mild or moderate in severity and transient in nature.

Table 2 lists adverse reactions that occurred in ? 0.2% patients who received DOTAREM.

Table 2: Adverse Reactions in Clinical Trials

Reaction	Rate (%) n = 2813
Nausea	0.6%
Headache	0.5%
Injection Site Pain	0.4%
Injection Site Coldness	0.2%
Burning Sensation	0.2%

Adverse reactions that occurred with a frequency < 0.2% in patients who received DOTAREM include: feeling cold, rash, somnolence, fatigue, dizziness, vomiting, pruritus, paresthesia, dysgeusia, pain in extremity, anxiety, hypertension, palpitations, oropharyngeal discomfort, serum creatinine increased and injection site reactions, including site inflammation, extravasation, pruritus, and warmth.

Adverse Reactions in Pediatric Patients

During clinical trials, 141 pediatric patients (7 aged < 24 months, 33 aged 2 - 5 years, 58 aged 6 - 11 years and 43 aged 12 - 17) received DOTAREM. Overall, 6 pediatric patients (4.3%) reported at least one adverse reaction following DOTAREM administration. The most frequently reported adverse reaction was headache

(1.5%). Most adverse events were mild in severity and transient in nature, and all patients recovered without treatment.

Postmarketing Experience

The following additional adverse reactions have been identified during postmarketing use of DOTAREM. Because these reactions are 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.

Table 3: Adverse Reactions in the Postmarketing Experience

Adverse Reaction	System Organ Class
bradycardia, tachycardia, arrhythmia	Cardiac Disorders
hypersensitivity / anaphylactoid reactions including cardiac arrest, respiratory arrest, cyanosis, pharyngeal edema, laryngospasm, bronchospasm, angioedema, conjunctivitis, ocular hyperemia, eyelid edema, lacrimation increased, hyperhidrosis, urticaria	Immune System Disorders
coma, convulsion, syncope, presyncope, parosmia, tremor	Nervous System Disorders
muscle contracture, muscle weakness	Musculoskeletal and Connective Tissue Disorders
diarrhea, salivary hypersecretion	Gastrointestinal Disorders
malaise, fever	General Disorders and Administration Site Conditions
NSF, in patients whose reports were confounded by the receipt of other GBCAs or in situations where receipt of other GBCAs could not be ruled out. No unconfounded cases of NSF have been reported with DOTAREM.	Skin and Subcutaneous Tissue Disorders
superficial phlebitis	Vascular Disorders