



GE Healthcare

101 Carnegie Center
Princeton, New Jersey 08540
USA

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Dear Healthcare Professional,

We would like to inform you of an issue that has recently come to our attention in April 2006. Two European hospitals have reported twenty-five cases of a rare disease called Nephrogenic Fibrosing Dermopathy or Nephrogenic Systemic Fibrosis (NFD/NSF) after the administration of Omniscan™ (gadodiamide) Injection, a gadolinium-based MRI contrast agent. These reported cases occurred over a period of four years.

NFD/NSF is a rare condition which has only been observed in patients with chronic, severely impaired renal function. At present there is no evidence that other patient groups are at risk of developing this disease. NFD/NSF leads to increased formation of connective tissue in the skin which then becomes thickened, coarse and hard sometimes leading to contractures.

GE Healthcare is working with the reporting hospitals and experts in the field to conduct a thorough investigation of these cases. We are also in close collaboration with the US Food and Drug Administration, the Danish Medicines Agency, and other EU Regulatory Authorities who are making further inquiries about the occurrence of this disease after the administration of all gadolinium-based MRI contrast media. To date, a causal relationship between NFD/NSF and these agents has not been established.

GE Healthcare is committed to the safety of patients receiving our products and in keeping our customers well informed about using them safely and effectively. Please contact Medical and Professional Services at 1 800 654 0118 for more information. As more information becomes available we will provide updates on the GE Healthcare web site <http://www.gehealthcare.com/omniscan/us/safety>. We also refer our customers to a source of information on NFD/NSF, including a registry of recorded cases (<http://www.icnfd.org>).

OMNISCAN is marketed in many countries world-wide and was first approved in 1993. It is estimated that about 5 million patients are administered OMNISCAN each year, and that a total of about 30 million patients have been administered OMNISCAN since its introduction to the market.

Sincerely,

Hugo Flaten
Vice President, Global Pharmacovigilance
GE Healthcare