

21 August 2006

Dear Healthcare Professional,

GE Healthcare B.V.¹ would like to inform you of an issue that has come to our attention. Two European hospitals² 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), a gadolinium-based MRI contrast agent. The reactions occurred over a period of four years.

NFD/NSF is a rare condition which according to available information 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. NFD/NSF can include systemic involvement and 5% of the cases have a rapidly progressive fulminant course.

GE Healthcare is working with the reporting hospitals and experts in the field to conduct a thorough investigation of these cases. This investigation is performed 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.

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

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 for more information 040 2991222/1223.

As more information becomes available GE Healthcare will provide updates on the GE Healthcare web site³ (www.gehealthcare.com)

All health care professionals are advised to report potential similar cases to *Nederlands Bijwerkingen Centrum Lareb*⁴ www.lareb.nl and GE Healthcare B.V.¹

Sincerely,



drs M. Adang
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¹ The marketing authorization holder for Omniscan®

² In Denmark (20 cases) and Austria (5 cases)

³ Information can also be located at (<http://www.icnfd.org>), which includes a registry of recorded NFD / NSF cases and on the FDA website www.fda.gov/cder/drug/infopage/gcca

⁴ Nederlands Bijwerkingen Centrum Lareb

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