GE Healthcare

Nycoveien 1-2
P.O. Box 4220 Nydalen
NO-0401 Oslo
Norway

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Dear Healthcare Professional,

IMPORTANT SAFETY INFORMATION – OMNISCAN & NEPHROGENIC SYSTEMIC FIBROSIS

In agreement with the European Regulatory Authorities, GE Healthcare would like to inform you about the introduction of important new safety information (contraindications and warnings) to the Summary of Product Characteristics (SmPC) for Omniscan™ (gadodiamide) injection concerning the potential risk of Nephrogenic Systemic Fibrosis (NSF). The information is summarised as follows:

Contraindication

- **Omniscan is contraindicated in patients with severe renal impairment (GFR<30 mL/min/1.73m^2)**
- **Omniscan is contraindicated in patients who have had or are undergoing liver transplantation**

Warning

- **Due to immature kidney function in neonates and infants up to 1 year of age, Omniscan should only be used in these patients after careful consideration**

Omniscan contains gadodiamide and is used as an intravenous contrast medium for cranial and spinal magnetic resonance imaging (MRI), for general MRI of the body and for cardiac MRI after intravenous administration.

NSF, also known as Nephrogenic Fibrosing Dermopathy (NFD), was first identified in 1997. It has only been observed in patients with renal insufficiency. Although most affected patients have advanced or end-stage kidney disease, a few have moderate renal dysfunction. At present, there is no evidence to suggest that there is any association between NSF and patient groups other than those for which Omniscan is contraindicated, as outlined above. NSF leads to excessive formation of connective tissue in the skin and internal organs. The skin becomes thickened, coarse and hard, sometimes leading to disabling contractures. NSF can include systemic involvement and may be fatal, with 5% of cases having a rapidly progressive fulminant course.

To date GE Healthcare has received 95 worldwide reports of NSF after Omniscan administration, usually associated with exposure at high doses. These reported cases have occurred over several years. Regulatory authorities have received additional reports of NSF after the administration of other gadolinium-based contrast agents, but the substantial majority of the reports relate to gadodiamide exposure.

In view of these serious reactions the following changes have been urgently introduced into the SmPC of Omniscan in agreement with the European regulatory authorities:

Section 4.3 (Contraindications)
Gadodiamide is contraindicated in patients with severe renal impairment (GFR< 30 ml/min/1.73m^2), and those who have had or are undergoing liver transplantation (see section 4.4 for Special Warnings and Precautions).

Section 4.4 (*Special warnings and precautions for use)*
Severe renal impairment and liver transplant patients:
There have been reports of nephrogenic systemic fibrosis (NSF) associated with use of gadodiamide and some other gadolinium-containing contrast agents in patients with severe renal impairment (GFR <30ml/min/1.73m^2) and those who have had or are undergoing liver transplantation. Therefore OMNISCAN® should not be used in these populations (see section 4.3 for Contraindications).

Neonates and Infants:
Due to immature kidney function in neonates and infants up to 1 year of age, OMNISCAN® should only be used in these patients after careful consideration.

Section 4.8 (*Undesirable effects)*
Cases of NSF have been reported with OMNISCAN®.

GE Healthcare is committed to the safety of patients receiving our products and in keeping our customers informed about using our products safely and effectively. GE Healthcare is closely following reported cases and working with hospitals and experts in the field to conduct a thorough investigation. We are engaging with global regulatory authorities who are making further inquiries about the occurrence of this disease after the administration of Omniscan or other gadolinium-based MR contrast media.

Please contact Medical and Professional Services directly at Tel no 01494 542612 with additional questions. Additional information on NSF is available from the Medicines and Healthcare products Regulatory Agency (MHRA) website http://www.mhra.gov.uk

GE Healthcare AS
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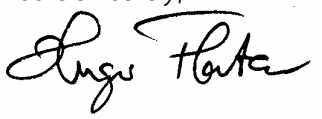
Any suspected adverse drug reactions should be reported to Medical and Professional Services at Tel no 01494 542612 and to the Medicines and Healthcare products Regulatory Agency (MHRA) by use of a Yellow Card, which is available from MHRA, CHM Freepost, London SW8 5BR or electronically via the MHRA website (http://www.mhra.gov.uk).

We will provide additional information as it becomes available.

Yours sincerely,



Hugo Flaten, MD
Vice President, Global Pharmacovigilance
GE Healthcare