



European Medicines Agency
Post-Authorisation Evaluation of Medicines for Human Use

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PUBLIC STATEMENT

Vasovist and nephrogenic systemic fibrosis (NSF)

The Pharmacovigilance Working Party (PhVWP) has discussed the issue of nephrogenic systemic fibrosis (NSF) associated with gadolinium-containing contrast agents for magnetic resonance imaging (MRI)¹ and informed the Committee for Medicinal Products for Human Use (CHMP) of the outcome at its January 2007 meeting. Most of the medicinal products are authorised nationally; only Vasovist is centrally authorised. Vasovist is currently marketed in 13 European Union countries.

Nephrogenic systemic fibrosis, which is also known as nephrogenic fibrosing dermopathy (NFD), is a rare, debilitating and sometimes fatal condition, that only occurs in patients with severe renal impairment. It is characterised by the formation of connective tissue in the skin, which becomes thickened, coarse and hard, sometimes leading to contractures and joint immobility. NSF has been associated with use of certain gadolinium-containing MRI contrast agents in patients with severe renal impairment.

The CHMP is not aware of reports of NSF with Vasovist. However, the CHMP, in line with the PhVWP conclusions, has requested the Marketing Authorisation Holder to introduce a warning in the Summary of Product Characteristics (SPC) about the occurrence of NSF in patients with severe renal impairment. This will be discussed further at the 2007 February CHMP meeting.

Detailed information on the PhVWP review, including an assessment report and a question and answer document, is available on the website of each national competent authority (<http://medagencies.org/>).

This safety concern will remain under continuous review, and new information and prescribing advice will be communicated as necessary on the EMEA website.

For further information, please contact:

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¹ The products reviewed were gadodiamide (Omniscan): gadobenidic acid (Multihance), gadobutrol (Gadovist), gadofosveset (Vasovist), gadopentetic acid (Magnevist), gadoteric acid (Artirem, Dotirem), gadoteridol (Prohance) and gadoxetic acid (Primovist).