

Home > Pharmacovigilance > Information on adverse drug reactions >

- **Information on adverse drug reactions**
- **Reporting adverse reactions in humans**
- **Reporting adverse reactions in animals**
- **Reporting adverse reactions in Clinical trials**
- **The Council for Adverse Drug Reactions**
- **Safety updates**
- **EudraVigilance**
- **The National Drug Interaction Database**

Investigation of the safety of MRI contrast medium Omniscan®

It has come to the attention of the Danish Medicines Agency that over a four year period 20 patients in Denmark and 5 patients in Austria have developed a very rare disease called 'Nephrogenic Fibrosing Dermopathy' or 'Nephrogenic Systemic Fibrosis' after the administration of Omniscan®. This disease causes the formation of connective tissue in the skin that is thickened, coarse and hard, sometimes leading to contractures. The disease has only been observed in patients with severely impaired renal function.

A causal relationship between the skin changes and Omniscan® has not been documented, but the adverse reaction reports have elicited a need for more detailed investigations. These will be carried out in close cooperation with the company which is marketing Omniscan® and with the physicians who have raised the suspicion, and also with the other Regulatory Authorities in EU.

The Danish Medicines Agency has contacted other Regulatory Authorities in EU. The inquiry applies to all gadolinium-containing MRI contrast media. This safety issue will later this year be discussed in EU's adverse reactions committee (the EU Pharmacovigilance Working Party).

The Danish Medicines Agency will come back to this issue when more information has been received.

Omniscan® is marketed in all of EU and in a number of countries outside the EU. Omniscan® has been marketed since 1993. It can be estimated that about 5 million patients are administered this contrast medium annually, and that a total of approx. 30 million patients have been investigated with Omniscan® since the introduction on the market. Currently about 17,500 patients examined Omniscan® in Denmark per year. Since January 2002 about 400 patients with severely impaired renal function have been examined. Of these there are observed 20 incidents of 'nefrogen fibroserende dermati'.

From the fact box to the right you can see summary of product characteristics for Omniscan®.

For **further information**, please contact [Doris I. Stenver](#), Consumer Safety, tel +454488 9247, cell phone +452246 0979.

The Danish Medicines Agency, 29 May 2006

Links

[Produktresumé Omniscan®](#)

Last updated - 11.09.2007

Add to My page ► Send article ► Top of