

MESSAGE FROM PROFESSOR G DUFF, CHAIRMAN, COMMITTEE
ON SAFETY OF MEDICINES.

2 February 2005

CEM/CMO/2005/

Dear Colleague,

Strattera (Atomoxetine) – Risk Of Hepatic Disorders

I am writing to inform you about the risk of rare, but sometimes severe, cases of hepatic disorders in association with the use of Strattera (atomoxetine). The risk is estimated at below 1 in 50,000 patients treated.

Strattera has been marketed in the UK since July 2004 but has been available in the United States since November 2002. It is an effective treatment for Attention-Deficit/Hyperactivity Disorder (ADHD), and is authorised for use in children of 6 years and older and in adolescents as part of a comprehensive treatment programme. Worldwide exposure is estimated at 2.3 million patients.

A total of 41 reports of hepatic disorders have been received worldwide, including two cases of severe acute hepatitis with markedly elevated hepatic enzymes (up to 40 times the ULN) and bilirubin (up to 12 times the ULN). There is no clear pattern in terms of onset time, and the reactions may occur after several months of treatment. In some cases liver function continues to worsen after the drug has been stopped. This does not appear to be a dose-related reaction.

In the UK, a total of 67 reports of suspected adverse drug reactions in association with atomoxetine have been received through the Yellow Card Scheme, including 3 reports of hepatic disorders (one case each of hepatitis, jaundice and elevated bilirubin levels).

Advice to prescribers:

- Due to the seemingly idiosyncratic nature of these reactions, routine monitoring of liver function is unlikely to be helpful in minimising the risk and is not recommended.
- All suspected hepatic reactions should be investigated. Atomoxetine should be discontinued in patients with jaundice or laboratory evidence of hepatic injury, and should not be restarted.
- Patients and the parents of children currently receiving atomoxetine should be advised of this risk and made aware of the possible signs and symptoms. An information sheet for parents and patients is attached.

The Committee on Safety of Medicines and the Medicines and Healthcare products Regulatory Agency are monitoring closely the safety of Strattera (atomoxetine). This particular safety signal is being actively investigated and any new information will be evaluated urgently.

Please report any suspected adverse reactions to atomoxetine via the Yellow Card Reporting Scheme to the Committee on Safety of Medicines/ Medicines and Healthcare products Regulatory Agency

For further information please call the Medicines and Healthcare products Regulatory Agency on 020 7084 2000.