

Medical & Allied Branch



Department of
**Health, Social Services
and Public Safety**

An Roinn

**Sláinte, Seirbhísí Sóisialta
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HSS(MD)7-2005

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Head of Professional Pharmacy Services, CSA

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Your Ref:
Our Ref:
Date: 3 February 2005

Dear Colleague

RE: STRATTERA (ATOMOXETINE) ? RISK OF HEPATIC DISORDERS

This letter provides prescribing advice on atomoxetine from Professor Gordon Duff, Chairman of the Committee on Safety of Medicines. It informs you about the risk of rare but sometimes severe cases of hepatic disorders in association with the use of atomoxetine.

Patients and parents of children currently receiving atomoxetine should be advised of the risk and be made aware of the possible symptoms. An information sheet for parents and patients is attached.

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.

Yours sincerely

HENRIETTA CAMPBELL (DR)
CHIEF MEDICAL OFFICER

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CHIEF NURSING OFFICER

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CHIEF PHARMACEUTICAL OFFICER

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From: Professor G Duff, Chairman, Committee on Safety of Medicines
Date: 3rd February 2005
Reference: CEM/CMO/2005/3

Dear Colleague,

Strattera (Atomoxetine) ? Risk Of Hepatic Disorders

I am writing to inform 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 upper limit of normal) and bilirubin (up to 12 times the upper limit of normal). 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 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 7273 0000.

Strattera (atomoxetine) ? Risk of liver problems

Information for Parents and Patients

What is Strattera (atomoxetine)?

Strattera (atomoxetine) is used to help control the symptoms of attention deficit hyperactivity disorder (ADHD - inability to pay attention and impulsiveness and hyperactivity) in children and adolescents. It increases the levels of noradrenaline, a natural chemical in the brain.

What is the new advice that has been issued?

The Chairman of the Committee on Safety of Medicines has written to all doctors and pharmacists informing them about the risk of liver problems in association with Strattera (atomoxetine). This risk is rare (estimated to occur in fewer than 1 in 50,000 patients treated) but in a small proportion of patients the reaction has been severe and resulted in liver damage and/or liver failure.

What should I do if my child is, or I am, taking Strattera (atomoxetine)?

Individuals taking Strattera (atomoxetine) who are feeling well need not be concerned. Anyone treated with Strattera (atomoxetine) who is concerned or unwell should see their doctor. Symptoms of liver problems include pain on the right side of the stomach just below the ribs, unexplained nausea (feeling sick), "flu-like" symptoms, dark urine and yellowing of eyes or skin (jaundice).

Do alternative treatments carry the same risk?

Methylphenidate (trade names are Ritalin, Concerta XL and Equasym), another medicine licensed for the treatment of ADHD, is also recognised rarely to cause liver problems.

What is being done to investigate the safety of this drug?

The Committee on Safety of Medicines and the Medicines and Healthcare products Regulatory Agency are keeping the safety of Strattera (atomoxetine) under close, constant scrutiny. This particular safety issue is being actively investigated and any new information will be urgently evaluated and, if necessary, new guidance will be issued.