

## **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. Warnings are present in product information for patients and prescribers.

#### **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.