

### **FDA approves first generic Strattera for the treatment of ADHD**

On May 30, 2017, the FDA approved the first generic versions of Strattera (atomoxetine) to treat attention-deficit/hyperactivity disorder (ADHD) in pediatric and adult patients. Four pharmaceutical industries including: Apotex Inc., Teva Pharmaceuticals USA Inc., Aurobindo Pharma Limited and Glenmark Pharmaceuticals Limited gained approval to market atomoxetine in multiple strengths. This will allow more affordable options depending on the patient's insurance.

Generic prescription drugs that have been approved by the FDA have the same high quality and strength as brand-name drugs.

Adverse effects for the nonstimulant atomoxetine include: initial somnolence and gastrointestinal tract symptoms, particularly if the dosage is increased too rapidly; decrease in appetite; increase in suicidal thought (less common); and hepatitis (rare). There is a black boxed warning on suicidal ideation in children and adolescents. Atomoxetine increased the risk of suicidal ideation in short-term studies in children or adolescents with ADHD. Patients must be closely monitored who are started on therapy for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior.

A pooled analyses of short-term (6- to 18-week), placebo-controlled trials of atomoxetine in children and adolescents (12 trials involving more than 2,200 patients, including 11 trials in ADHD and 1 trial in enuresis) have revealed a greater risk of suicidal ideation early during treatment in those receiving atomoxetine compared with placebo. Therefore, closely monitoring the patient is imperative especially for initial therapy. The average risk of suicidal ideation in patients receiving atomoxetine was 0.4% compared with none in placebo-treated patients. No suicides occurred in these trials.

#### References:

- FDA Staff. FDA approves first generic Strattera for the treatment of ADHD. FDA. Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm561096.htm>.
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- Subcommittee on Attention-Deficit/Hyperactivity Disorder, Steering Committee on Quality Improvement and Management, Wolraich M, et al. ADHD: clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. *Pediatrics*. 2011;128(5):1007-22.