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STRATTERA™
IMPORTANT DOSING AND SAFETY INFORMATION

SUBJECT: Strattera™ (atomoxetine hydrochloride)
Treatment of ADHD – Important Dosing and Safety Information

Dear Healthcare Professional:

Eli Lilly Canada is pleased to inform you of the launch and availability of Strattera™ (atomoxetine hydrochloride) for the treatment of Attention Deficit/Hyperactivity Disorder (ADHD) in children (6 years and above), adolescents and adults. Strattera was approved by Health Canada on December 24, 2004. Strattera works differently from other approved medications for the treatment of ADHD. Strattera is not a stimulant drug and is not a controlled substance.

This letter provides information on the safety of Strattera (see Hepatic Effects, below), and the importance of gradual titration of Strattera to reach an effective dose. It is important that patients are maintained at each dose level for a sufficient length of time to elicit clinical response. The dose should then be increased to the next level only if needed, for patients who have not achieved optimal clinical response (see Recommended Dose and Dosage Adjustment, below). Do not exceed the recommended initial dose, subsequent dose escalations and maximum daily dose of Strattera.

General

Strattera has a gradual onset of action and requires slow titration to reach an effective maintenance dose. More rapid dose escalation may be associated with increased rates of somnolence and digestive system complaints. Improvement of ADHD symptoms is generally observed within 1 to 4 weeks of initiating therapy.

Strattera is intended for oral administration and may be taken with or without food, either as a single daily dose in the morning or as divided doses in the morning and late afternoon/early evening. Strattera may be discontinued without tapering the dose. Only whole capsules should be administered.

Please review the complete Product Monograph which is enclosed with this letter, for detailed information prior to prescribing Strattera.

Recommended Dose and Dosage Adjustment

a) *In Children (6 years and over) and Adolescents, up to 70 kg body weight:* The dosing regimen for Strattera is based on the patient's body weight, as shown in the Table below.

Recommended Strattera Dose Titration in Children and Adolescents up to 70 kg Body Weight

Body Weight	Starting Dose (approx. 0.5 mg/kg/day)	Intermediate Dose (approx. 0.8 mg/kg/day)	High Dose (approx 1.2 mg/kg/day)
20-29 kg	10 mg	18 mg	25 mg
30-44 kg	18 mg	25 mg	40 mg
45-64 kg	25 mg	40 mg	60 mg
65-70 kg	40 mg	60 mg	80 mg

Strattera should be initiated at a total daily dose of approximately 0.5 mg/kg. The initial dose should be maintained for a minimum of 10 days. After this time, if patients have not experienced clinically significant symptom response at the initial dose, the dose may be increased to the intermediate dose level, which also should be maintained for a minimum of 10 days. According to clinical response and tolerability, the dose may be increased to 1.2 mg/kg/day (actual dose may be between 0.9 to 1.3 mg/kg/day, depending on the patient's weight and available dosage strengths of Strattera). After a minimum of 30 days, dose should be reassessed and adjusted according to clinical response and tolerability.

Do not exceed the recommended maximum total daily dose of 1.4 mg/kg or 100 mg, whichever is less, as potentially serious side-effects could result with overdosing.

Most common adverse reactions with Strattera are abdominal pain, decreased appetite and nausea / vomiting. Growth rates (weight and height) after 2 years of treatment are near normal.

b) *In Adults, and in Children/Adolescents Over 70 kg Body Weight:* Strattera should be initiated at a total daily dose of 40 mg. The initial dose should be maintained for a minimum of 10 days. After this time, if patients have not experienced clinically significant symptom response at the initial dose, the dose may be increased to the intermediate dose level of 60 mg, which also should be maintained for a minimum of 10 days. According to clinical response and tolerability, the dose may be increased to 80 mg. After 2 to 4 additional weeks, the total daily dose may

be increased to a maximum of 100 mg in patients who have not achieved an optimal response.

Do not exceed the recommended maximum total daily dose of 100 mg, as potentially serious side-effects could result with overdosing.

Warning on Hepatic Effects

Post-marketing reports indicate that Strattera can cause severe liver injury in rare cases. Although no evidence of liver injury was detected in clinical trials, there have been 2 reported cases of markedly elevated hepatic enzymes and bilirubin, in the absence of other obvious explanatory factors, out of more than 2 million patients during the first 2 years of post-marketing experience.

Strattera should be discontinued in patients with jaundice or laboratory evidence of liver injury, and should not be restarted. Laboratory testing to determine liver enzyme levels should be done upon the first symptom or sign of liver dysfunction (e.g., pruritus, dark urine, jaundice, right upper quadrant tenderness, or unexplained "flu-like" symptoms).

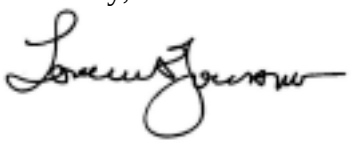
Post-Market Experience

During the first 24 months of post-market experience outside of Canada, it is estimated that over 2 million patients have been treated with Strattera, for 600,000 patient-years of therapy.

Lilly routinely assesses safety information as it becomes available and updates Product Monographs accordingly. Eli Lilly Canada is committed to providing you with the most current and complete product information available for the management of patients receiving Strattera.

Inquiries from healthcare professionals should be directed to Eli Lilly Canada Customer Response Centre at 1-888-545-5972 between 8 a.m. and 6 p.m. EST, or by fax: 1-888-898-2961.

Sincerely,



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