STRATTERA CAPSULE®

Atomoxetine HCl (10 mg, 18 mg, 25 mg, 40 mg, 60 mg)

What is in this leaflet

What Strattera is used for

Strattera contains atomoxetine and is used to treat attention-deficit and hyperactivity disorder (ADHD). ADHD is a behavioural disorder that causes lack of focus and/or hyperactivity that is much more frequent or severe than others who are close in age or development. Strattera is used in:

- children over six years of age
- young people
- adults

It is used only as a part of the total treatment of the disease which also requires treatments which do not involve medicines, such as counselling and behavioural therapy.

It is not for use as a treatment for ADHD in children under 6 years of age as it is not known if the drug works or is safe in these people.

In adults, Strattera is used to treat ADHD when the symptoms are very troublesome and affect your work or social life and when you have had symptoms of the disease as a child.

How Strattera works

Strattera increases the amount of noradrenaline in the brain. This is a chemical in the brain that is produced naturally, which increases attention and decreases impulsiveness and hyperactivity in patients with ADHD. This medicine has been prescribed to help control the symptoms of ADHD. This medicine is not a stimulant and is therefore not addictive.

It may take a few weeks after you start the medicine for your symptoms to fully improve.

Before you use Strattera

- *When you must not use it*

- if you are allergic (hypersensitive) to atomoxetine or any of the other ingredients of Strattera.
- if you took a medicine known as a monoamine oxidase inhibitor (MAOI), for example phenelzine, in the last two weeks. As MAOI is sometimes used for depression and other mental health problems; taking Strattera with an MAOI could cause serious side effects or be life-threatening. (You also need to wait at least 14 days after you stop taking Strattera, before you take an MAOI).
- if you have an eye disease called narrow-angle glaucoma (increased pressure in your eye)
- if you have previously taken Strattera but had to discontinue your treatment due to jaundice (yellowing of the skin or eye) or laboratory evidence of liver injury.
- if you have serious problems with your heart which may be affected by an increase in heart rate and/or blood pressure as this may be an effect of Strattera.
- if you have serious problems with the blood vessels in your brain- such as a stroke, swelling and weakening of part of a blood vessel (aneurysm) or narrowed or blocked blood vessels
- if you have a tumour of your adrenal gland (phaeochromocytoma).

Strattera should not be used in children under six years of age.

Pregnancy and breast-feeding

It is not known if Strattera can affect an unborn baby or pass into breast milk.

- Strattera should not be used during pregnancy, unless your doctor has advised you to do so.
- You should either avoid taking Strattera if you are breast-feeding or discontinue breast-feeding.

If you:

- are pregnant or breast-feeding
- think you may be pregnant
- are planning to have a baby
- planning to breast-feed your baby ask your doctor or pharmacist for advice before taking Strattera.

- *Before you start to use it*

Talk to your doctor before taking Strattera if you have:

- thoughts about killing yourself or trying to kill yourself.
- problems with your heart (including heart defects) or an increased heartbeat. Strattera can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects.
- high blood pressure. Strattera can increase blood pressure.
- low blood pressure. Strattera can cause dizziness or fainting in people with low blood pressure.
- problems with sudden changes in your blood pressure or your heart rate.
- cardiovascular disease or past medical history of stroke.
- liver problems. You may need a lower dose.
- psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious.
- mania (feeling elated or over-excited, which causes unusual behavior) and agitation.

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- aggressive feelings.
- unfriendly and angry (hostility) feelings.
- a history of epilepsy or have had seizures for any other reason. Strattera might lead to an increase in seizure frequency.
- different moods than usual (mood swings) or feel very unhappy.
- hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words (motion tics).

Tell your doctor or pharmacist if any of the above applies to you before starting treatment. This is because Strattera can make these problems worse. Your doctor will want to monitor how the medicine affects you.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking, have recently taken or plan to take any other medicines. This includes non-prescription medicines. Your doctor will decide if you can take Strattera with your other medicines and in some cases your doctor may need to adjust your dose or increase your dose much more slowly.

Do not take Strattera with medicines called MAOI's (monoamine oxidase inhibitors) used for depression.

If you are taking other medicines, Strattera may affect how well they work or may cause side effects. It you are taking any of the following medicines, check with your doctor or pharmacist before taking Strattera:

- medicines that increase blood pressure or are used to control blood pressure
- medicines such as antidepressants, for example imipramine, venlafaxine and mirtazapine
- some cough and cold remedies which contain medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of these product
- some medicines used to treat mental health conditions
- medicines that are known to increase the risk of seizures
- some medicines that cause Strattera to stay in the body for longer than normal (such as quinidine and terbinafine)
- salbutamol (a medicine to treat asthma) when taken by mouth or injected may make you feel as if your heart is racing, but this will not make your asthma worse.

The medicine below may lead to an increased risk of an abnormal rhythm of the heart when taken with Strattera:

- medicines used to control the rhythm of the heart,
- medicines for malaria prevention and treatment,
- some antibiotic medicines (such as erythromycin and moxifloxacin)

If you are in any doubt about whether any medicines you are taking are included in the list above, ask your doctor or pharmacist before taking Strattera.

How to use Strattera

- *How much to use*

If you are a child or teenager (6 years or older):

Your doctor will tell you how much Strattera you should take and will calculate this according to your weight. He/she will normally start you on a lower dose before increasing the amount of Strattera you need to take according to your body weight.

- *Body weight up to 70kg*: a starting total daily dose of 0.5mg per kilogram of body weight for a minimum of 7 days. Your doctor may then decide to increase this to the usual maintenance dose of about 1.2 mg per kilogram of body weight daily.
- *Body weight over 70 kg*: a starting total daily dose of 40 mg for a minimum of 7 days. The recommended maintenance dose is 80mg. the maximum daily dose your doctor will prescribe is 100 mg.

Adults

- Strattera should be started at a total daily dose of 40 mg for a minimum of 7 days. Your doctor may then decide to increase this to the usual maintenance dose of 80mg-100mg daily. The maximum daily dose your doctor will prescribe is 100 mg.

If you have problems with your liver your doctor may prescribe a lower dose. Safety and effectiveness in elderly patients older than 65 years have not been established.

- *When to use it*

- Always take Strattera as your doctor has told you. This is usually one or two times a day (morning and late afternoon or early evening)
- Your doctor may change your dosing schedule to twice a day if you experience sleepiness or feeling sick when you take Strattera once a day
- The capsules should be swallowed, either with or without food
- The capsules should not be opened and the contents inside the capsules should not be removed and taken in any other way
- Taking the medicine at the same time each day may help you to remember to take it

- *How long to use it*

Continue taking Strattera for as long as your doctor recommends.

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Long-term treatment
Strattera does not need to be taken for ever. If you take Strattera for more than a year, your doctor will review your treatment, to see if the medicine is still needed.

- *If you forget to use it*
If you miss a dose, you should take it as soon as possible, but you should not take more than your total daily dose in any 24-hour period. Do not take a double dose to make up for forgotten doses.

If you stop taking Strattera there are not normally any side effects but your ADHD symptoms may return. You should talk to your doctor first before you stop treatment.

- *If you use too much (overdose)*
If you take more Strattera than you should contact your doctor or the nearest hospital casualty department immediately and tell them how many capsules you have taken. The most commonly reported symptoms accompanying overdoses were gastrointestinal symptoms, sleepiness, dizziness, tremor, and abnormal behavior.

While you are using it
- *Things you must do*
See your doctor immediately. This is because your doctor will want to check how the medicine is working.

Do not stop taking the medicine without first talking to your doctor.

Your doctor may stop your medicine to see if it is still needed, if your take for more than a year.

- *Things you must not do*
Do not stop taking the medicine unless advised by your doctor.
Do not take any new medicines without consulting your doctor.

Do not give Strattera to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*
Suicidal ideation
Strattera increased the risk of suicidal ideation in children. Pay close attention to your child whenever Strattera is started or its dose is changed. Contact your doctor or a paediatric psychiatrist straight away or go to the nearest hospital for treatment if you notice any sudden change in your child's behavior (see **Side effects**).

Orthostatic hypotension
You may experience orthostatic hypotension (an abnormal decrease in blood pressure when a person stands up) while you are using Strattera. If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Driving and using machines
If your feel tired, sleepy or dizzy you should not operate hazardous machinery.

Important information about the content of the capsules
Strattera capsules are not intended to be opened as the contents of the capsule can irritate the eye. If the contents of the capsules come into contact with the eye, the affected eye should be flushed immediately with water, and medical advice obtained. Hands and any other part of the body that may have come into contact with the capsule contents should also be washed as soon as possible.

Side effects
Like all medicines, Strattera can cause side effects, although not everybody gets them. Although some peoples get side effects most people find that Strattera helps them. Your doctor will talk to you about theses sides effects.

The *very common* side effects in children and young people are:
- appetite decreased, headache, sleepiness, abdominal pain, nausea, vomiting, increased blood pressure, increased heart rate (pulse)

The *very common* side effects in adults are:
- appetite decreased, difficulty falling or staying asleep, headache, dry mouth, nausea, vomiting, increased blood pressure, increased heart rate (pulse)

Tell your doctor immediately or go to the Emergency Department of your nearest hospital if you notice any of the following in you/ your child while taking STRATTERA:
- sudden change in moods and behavior e.g. new or worse depression, new or worse anxiety, new or worse irritability, thoughts of suicide or attempts to self-harm.
- Signs of liver injury such as dark urine, yellowing of the skin or eyes, severe cramps of the stomach, or unexplained nausea, fatigue, lethargy, itching or flulike symptoms
- Fast or irregular heart beat
- Fainting
- New-onset seizure or increase in frequency of seizures

Effects on growth
Some children experience reduced growth (weight and height) when they start taking Strattera. However, with long-term treatment, children recover to the weight and height for their age range.

Your doctor will watch your child's height and weight over time. If your

child is not growing or gaining weight as expected, your doctor may change your child's dose or decide to stop Strattera temporarily.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Strattera

- *Storage*

Keep out of the reach and sight of children.

Do not store above 25˚C.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste.

Product Description

- *What it looks like*

- Capsules, hard, 10 mg (white, imprinted Lilly 3227/10 mg)
- Capsule, hard, 18 mg (gold/ white, imprinted Lilly 3238/ 18 mg)
- Capsule, hard, 25 mg (blue/ white, imprinted Lilly 3228/ 25 mg)
- Capsule, hard, 40 mg (blue, imprinted Lilly 3229/ 40 mg)
- Capsule, hard, 60 mg (blue/ gold, imprinted Lilly 3239/ 60 mg)
- Strattera capsules are available in packs of 28 capsules.

- *Ingredients*

- Active ingredient(s)
  The active substance is atomoxetine hydrochloride. Each hard capsule contains atomoxetine hydrochloride equivalent to 10 mg, 18 mg, 25 mg, 40 mg, or 60 mg of atomoxetine.
- Inactive ingredients
  - *Other ingredients*: pregelatinised starch and dimeticone.
  - *Capsule shells*: sodium laurylsulfate and gelatin.
  - *Capsule shell colourants:*
    - Yellow iron oxide E172 (18 mg and 60 mg)
    - Titanium dioxide E171 (10 mg, 18 mg, 25 mg, 40 mg, and 60 mg)
    - FD&C blue 2 (indigo carmine) E132 (25 mg, 40 mg and 60 mg)
    - Edible black ink (containing shellac and black iron oxide E172)

- *MAL number(s):*

Strattera 10 mg Capsule (MAL20051402A)
Strattera 18 mg Capsule (MAL20051403A)
Strattera 25 mg Capsule (MAL20051404A)
Strattera 40 mg Capsule (MAL20051405A)
Strattera 60 mg Capsule (MAL20051406A)

Manufacturer

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Product Registration Holder

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