Patient Leaflet in Accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Strattera® 10 mg
Hard capsules
Active ingredient and its quantity:
Each capsule contains:
Atomoxetine 10 mg

Strattera® 18 mg
Hard capsules
Active ingredient and its quantity:
Each capsule contains:
Atomoxetine 18 mg

Strattera® 25 mg
Hard capsules
Active ingredient and its quantity:
Each capsule contains:
Atomoxetine 25 mg

Strattera 40® mg
Hard capsules
Active ingredient and its quantity:
Each capsule contains:
Atomoxetine 40 mg

Strattera 60® mg
Hard capsules
Active ingredient and its quantity:
Each capsule contains:
Atomoxetine 60 mg

Strattera 80® mg
Hard capsules
Active ingredient and its quantity:
Each capsule contains:
Atomoxetine 80 mg

Strattera 100® mg
Hard capsules
Active ingredient and its quantity:
Each capsule contains:
Atomoxetine 100 mg

Inactive ingredients and allergens: see "important information about the ingredients of this medicine" in section 2 and section 6 "additional information.

Important information you need to know about the medicine
Clinical studies carried out on **Strattera** have shown an increase in the frequency of suicidal thoughts and suicide attempts in children and adolescents. Tell your doctor if your child (or if there is a family history):

1. suffers from bipolar disorder
2. has suffered from suicidal thoughts or has attempted suicide before starting treatment with **Strattera**

The risk of suicidal thoughts or suicide attempts is higher at the beginning of treatment and when changing the dose.
During treatment with **Strattera**, you must closely monitor your child's mood and behavior. If you have any of the following symptoms, contact your doctor immediately:
anxiety, irritability, panic attack, sleep disorders, over excitement, hostility, aggressiveness, impulsive, restlessness, mania, depression, suicidal thoughts.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, please contact your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

Strattera is intended for children over 6 years of age.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Strattera contains atomoxetine and is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD). It is intended for:

- children over 6 years of age
- young people
- adults

Strattera should be used only as a part of the total treatment of the disease which also requires treatments which do not involve medicines, such as counseling and behavioral therapy.

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

Therapeutic group:
Centrally acting sympathomimetics.

How the medicine works
Strattera increases the amount of noradrenaline in the brain. Noradrenaline is a chemical substance that is produced naturally, and 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.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if you or your child:

- are hypersensitive (allergic) to atomoxetine or to any of the other ingredients this medicine contains (listed in section 6).
- took a medicine known as a monoamine oxidase inhibitor (MAOI), for example phenelzine, in the last two weeks. An MAOI is sometimes used to treat depression and other mental-health problems. Taking **Strattera** with an MAOI could cause serious side effects or be life-threatening. In addition, you must wait at least 14 days after you stop taking **Strattera** before you take an MAOI.
- have an eye disease called narrow-angle glaucoma (increased pressure in your eye).
- have serious problems with your heart which may be affected by an increase in heart rate and/or blood pressure, as these may be side effects of **Strattera.**
- 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 narrow or blocked blood vessels.
- have a tumor of your adrenal gland (phaeochromocytoma).

Do not take **Strattera** if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before you take **Strattera**. This is because **Strattera** can make these problems worse.

Special warnings regarding the use of this medicine
Both children and adults should be aware of the following warnings and precautions.
Talk to your doctor before starting treatment with Strattera if:

- you have suicidal thoughts or have attempted suicide.
- you suffer from 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.
- you have high blood pressure. **Strattera** can increase blood pressure.
- you have low blood pressure. **Strattera** can cause dizziness or fainting in people with low blood pressure.

- you have problems with sudden changes in your blood pressure or your heart rate.
- you have a cardiovascular disease or past medical history of stroke.
- you have liver problems. You may need a lower dose.
- you have psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious.
- you suffer from mania (feeling elated or over-excited, which causes unusual behavior) and agitation.
- you have aggressive feelings.
- you have unfriendly and angry (hostility) feelings.
- you have a history of epilepsy or have had seizures for any other reason. **Strattera** might lead to an increase in seizure frequency.
- you have different moods than usual (mood swings) or feel very unhappy.
- you suffer from hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words.

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

Tests that your doctor will perform before you start taking Strattera
These tests are to decide if **Strattera** is the correct medicine for you.

Your doctor will measure your:
- blood pressure and heart rate (pulse) before and during treatment with **Strattera**
- height and weight if you are a child or teenager during treatment with **Strattera**

Your doctor will talk to you about:
- any other medicines you are taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you or your family may have

It is important that you provide as much information as you can. This will help your doctor decide if **Strattera** is the correct medicine for you. Your doctor may decide that other medical tests are needed before you start taking this medicine.

Drug interactions
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including non-prescription medicines and nutritional supplements.
Your doctor will decide if you can take **Strattera** with your other medications 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 MAOIs (monoamine oxidase inhibitors) used for treating depression. See section 2 “Do not take **Strattera**”.

If you are taking other medicines, **Strattera** may affect how well they work or may cause side effects. If 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, mirtazapine, fluoxetine and paroxetine
- some cough and cold remedies which contain medicines that can affect blood pressure. It is important to check with your pharmacist when you get such medicines
- 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 medicines 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 which change the concentration of salts in the blood
- medicines for malaria prevention and treatment
- some antibiotic medicines (such as erythromycin and moxifloxacin)

If you are not sure about whether any medicines you are taking are included in the list above, ask your doctor or pharmacist before taking **Strattera**.

Use of Strattera and food
Strattera can be taken with or without food.

Pregnancy and breastfeeding
It is not known if this medicine can affect the fetus or pass into breast milk.
- This medicine should not be used during pregnancy, unless your doctor has advised you to do so.
- You should either avoid taking this medicine if you are breastfeeding or discontinue breastfeeding.

If you are:
- pregnant or breastfeeding
- thinking that you may be pregnant or are planning to get pregnant
- planning to breastfeed your baby

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
You may feel tired, sleepy or dizzy after taking **Strattera**. You should be careful if you are driving a car or operating machinery until you know how **Strattera** affects you. If you feel tired, sleepy or dizzy you should not drive or operate machinery.

Important information about the ingredients of this medicine
Do not open the capsules because 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.

3. HOW TO USE THIS MEDICINE?

- Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this preparation. The dosage and manner of treatment will be determined only by the doctor. The usual dose is once or twice a day (morning and late afternoon or early evening).
- Children should not take this medicine without the help from an adult.
- If you are taking **Strattera** once a day and experience sleepiness or feel sick, your doctor may change your treatment schedule to twice a day.
- The capsules should be swallowed whole, 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 remember to take it.

The dosage and manner of treatment will be determined only by the doctor.

If you have problems with your liver, your doctor may prescribe a lower dose.

Do not exceed the recommended dose.

Tests and follow-up:
The doctor will perform several tests
- Before beginning treatment - to make sure that **Strattera** is safe and will be of benefit.
- After treatment starts - will be performed at least every 6 months, but possibly more often.

Tests will also be performed when the dose is changed. These tests will include:
- measuring height and weight in children and young people
- measuring blood pressure and heart rate
- checking whether you have any problems or if side effects have worsened during treatment with **Strattera**

If you have taken a higher dose, contact your doctor or the nearest hospital Emergency Room immediately, bring the medicine package with you and let them know how many capsules you have taken. The most commonly reported symptoms accompanying overdose are gastrointestinal symptoms, sleepiness, dizziness, tremor, and abnormal behavior.

If you forgot to take Strattera
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 a forgotten dose.

Treatment should be continued as recommended by the doctor.
Even if there is an improvement in your health, do not stop taking this medicine without consulting your doctor.

If you stop taking Strattera
If you stop taking **Strattera** there are usually no side effects, but your ADHD symptoms may return. Contact your doctor before stopping treatment.

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

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any questions about the use of this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS
As with any medicine, the use of **Strattera** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Some side effects could be serious.

You should stop taking Strattera and contact your doctor immediately if you have any of the following:

- dark urine
- yellow skin or yellow eyes
- tummy pain which is sore when you press it (tenderness) on the right side just below your ribs
- a feeling of sickness (nausea) that is unexplained
- tiredness
- itching
- feeling that you are coming down with the flu

See your doctor immediately if you have one or more of the following side effects:
Uncommon side effects (may affect up to 1 in 100 people)
- feeling or having a very fast heartbeat, abnormal rhythms of the heart
- thinking about or feeling like committing suicide
- feeling aggressive
- feeling unfriendly and angry (hostility)
- mood swings or mood changes
- serious allergic reaction with symptoms of
    - swelling of the face and throat
    - difficulty breathing
    - hives (small raised, itchy patches of skin)
- seizures
- psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious

Children and young adults under 18 years of age have an increased risk of side effects such as:
- thinking about or feeling like committing suicide (may affect up to 1 in 100 people)
- mood swings or mood changes (may affect up to 1 in 10 people)

Adults have a reduced risk (may affect up to 1 in 1,000 people) **of side effects such as:**
- seizures
- psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious

Rare side effects (may affect up to 1 in 1,000 people)
- liver injury

Other side effects reported include the following. If they get serious, tell your doctor or pharmacist.

Very common side effects (may affect more than 1 in 10 people)	
CHILDREN and YOUNG PEOPLE over the age of 6	**ADULTS**
- headache - pain in the stomach - decreased appetite (not feeling hungry) - nausea or vomiting - sleepiness - increased blood pressure - increased heart rate (pulse) These side effects may disappear after a while in most patients.	- nausea - dry mouth - headache - decreased appetite (not feeling hungry) - problems getting to sleep, staying asleep and waking early - increased blood pressure - increased heart rate (pulse)

Common side effects (may affect up to 1 in 10 people)	
CHILDREN and YOUNG PEOPLE over the age of 6	**ADULTS**
- being irritable or agitated - problems sleeping including waking early - depression - feeling sad or hopeless - feeling anxious - tics - large pupils (the dark center of the eye) - dizziness - constipation - loss of appetite - upset stomach, indigestion - swollen, reddened and itchy skin - rash - feeling lazy (lethargy) - chest pain - tiredness - weight loss	- feeling agitated - decreased interest in sex - sleep disturbance - depression - feeling sad or hopeless - feeling anxious - dizziness - an abnormal taste or change in taste that will not go away - tremor - tingling or numbness in the hands or feet - sleepiness, drowsy, feeling tired - constipation - stomach ache - indigestion - wind (flatulence) - vomiting - hot flush or flushing - feeling or having a very fast heartbeat - swollen, reddened and itchy skin - increased sweating - rash - difficulty urinating, frequent or hesitant urination, pain during urination - inflammation of the prostate gland (prostatitis) - groin pain in men - failure to obtain an erection - retarded orgasm - difficulty maintaining an erection - menstrual cramps - lack of strength or energy - tiredness - feeling lazy (lethargy) - chills - feeling irritable, jittery - feeling thirsty - weight loss

Uncommon side effects (may affect up to 1 in 100 people)	
CHILDREN and YOUNG PEOPLE over the age of 6	**ADULTS**
- fainting - tremor - migraine - blurred vision - abnormal skin sensation, such as burning, prickling, itching, or tingling	- restlessness - tics - fainting - migraine - blurred vision - abnormal heart rhythm (QT

- tingling or numbness in the hands or feet - seizure (fits) - feeling or having a very fast heartbeat (QT prolongation) - shortness of breath - increased sweating - itchy skin - lack of strength or energy	prolongation) - feeling cold in fingers and toes - chest pain - shortness of breath - raised red itchy rash (hives) - muscle spasms - an urge to urinate - abnormal or absence of orgasm - irregular menstruation - ejaculation failure

Rare side effects (may affect up to 1 in 1,000 people)	
CHILDREN and YOUNG PEOPLE over the age of 6	**ADULTS**
- poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease) - difficulty urinating, frequent or hesitant urination, pain during urination - prolonged and painful erections - groin pain in males	- poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease) - prolonged and painful erections

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.

If a side effect occurs, if one of the side effects gets worse or if you have a side effect not mentioned in the leaflet, consult your doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects due to drug treatment" that can be found on the Home Page of the Ministry of Health's website (www.health.gov.il), which refers to the online form for reporting side effects, or via the following link:
https://sideeffects.health.gov.il

5. HOW TO STORE THIS MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use this medicine after the expiration date (exp. date) that appears on the package and blister. The expiry date refers to the last day of that month.
- **Strattera** 10 mg, 18 mg, 25 mg, 40 mg and 60 mg: Store in the original package at a temperature below 300C in order to protect from light and moisture.
- **Strattera** 80 mg and 100 mg: Store in the original package at a temperature below 250C in order to protect from light and moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:
Pregelatinised starch, dimeticone 350 centistokes

The capsule shell contains:
Gelatin and sodium laurilsulfate

The capsule shell colorants are:
Yellow iron oxide (18 mg, 60 mg, 80 mg and 100 mg)
Titanium dioxide (10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg)
FD&C blue 2 (indigo carmine) (25 mg, 40 mg and 60 mg)
Red iron oxide (80 mg and 100 mg)
Edible black ink

What the medicine looks like and contents of the pack:
Strattera 10 mg: Capsule, hard, 10 mg (white, imprinted Lilly 3227/10 mg, approximately 15.5-16.1 mm length)
Strattera 18 mg: Capsule, hard, 18 mg (gold/white, imprinted Lilly 3238/18 mg, approximately 15.5-16.1 mm length)
Strattera 25 mg: Capsule, hard, 25 mg (blue/white, imprinted Lilly 3228/25 mg, approximately 15.5-16.1 mm length)
Strattera 40 mg: Capsule, hard, 40 mg (blue, imprinted Lilly 3229/40 mg, approximately 15.5-16.1 mm length)
Strattera 60 mg: Capsule, hard, 60 mg (blue/gold, imprinted Lilly 3239/60 mg, approximately 17.5-18.1 mm length)
Strattera 80 mg: Capsule, hard, 80 mg (brown/white, imprinted Lilly 3250/80 mg, approximately 17.5-18.1 mm length)
Strattera 100 mg: Capsule, hard, 100 mg (brown, imprinted Lilly 3251/100 mg, approximately 19.2-19.8 mm length)

Strattera capsules are available in packs of 28 capsules.

License holder and address: Eli Lilly Israel Ltd., 4 HaSheizaf Street, P.O.Box 4246, Ra'anana 4366411

Manufacturer and address: Eli Lilly and Company Ltd., Indianapolis, Indiana, USA

Revised in February 2021 according to MOH's guidelines**.**

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Strattera 10 mg: 156-69-34554-00
Strattera 18 mg: 156-71-34590-00
Strattera 25 mg: 156-70-34584-00
Strattera 40 mg: 156-72-34585-00
Strattera 60 mg: 156-73-34586-00
Strattera 80 mg: 156-74-34587-00
Strattera 100 mg: 156-75-34588-00