Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is to be supplied by a doctor’s prescription only

# Strattera 4 mg/ml Oral Solution

**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.

**The active ingredient and its concentration:**

Each ml of oral solution contains atomoxetine hydrochloride equivalent to 4 mg of atomoxetine.

For a list of inactive ingredients, see section 6.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you or your child has 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.

The medicine is intended for adults and children over 6 years of age.

## 1. WHAT IS THIS MEDICINE INTENDED FOR?

- **Straterra 4 mg/ml Oral Solution** contains atomoxetine and is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).
  For use in:
  - children over 6 years of age
  - adolescents
  - adults

  The medicine should be used only as part of a comprehensive treatment of the illness that also includes non-drug treatment, such as counselling 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.

**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 drug, and is therefore not addictive. It may take a few weeks after you start the medicine for your symptoms to fully improve.

**Therapeutic group:** central nervous system stimulant.

## 2. BEFORE USING THE MEDICINE

| Do not use the medicine if: |
| --- |
| • you or your child is sensitive (allergic) to the active ingredient (atomoxetine hydrochloride) or to any of the other ingredients this medicine contains (see section 6).<br>• you took a medicine known as a monoamine oxidase inhibitor (MAOI), such as 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. |

- you have an eye disease called narrow-angle glaucoma (increased pressure in your eye).
- you 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.**
- 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 narrow or blocked blood vessels.
- you have a tumor of your adrenal gland (phaeochromocytoma).

Do not take **Strattera 4 mg/ml Oral Solution** if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine. This is because **Strattera** can make these problems worse.

## Special warnings regarding the use of this medicine

Both adult and children should be aware of the following warnings and precautions.

**Before treatment with Strattera 4 mg/ml Oral Solution tell your doctor 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 you or your child feel very unhappy.
- you suffer from hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words.

Before beginning treatment with **Strattera**, tell your/your child's doctor or pharmacist if any of the above side effects applies to you. 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 using this medicine:**

These tests are to decide if **Strattera 4 mg/ml Oral Solution** is the correct medicine for you. Your doctor:

- will measure your blood pressure and heart rate (pulse) before and during treatment with **Strattera**.
- will measure your 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 or your child are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements.**

Your/your child's 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 or your child are taking other medicines, **Strattera** may affect how well they work or may cause side effects. If you or your child 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 this medicine and food**

This medicine can be taken with or without food.

The oral solution should not be mixed in food or water as this can decrease the amount taken or make the taste less pleasant.

### 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, think that you may be pregnant or are planning a pregnancy, are 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 hazardous machinery until you know how **Strattera** affects you. Do not drive or operate machinery if you feel tired, sleepy or dizzy. As for children, they should be cautioned against riding bicycles or playing near the road etc.

### Important information about the oral solution

This oral solution can irritate the eye. If the oral solution comes 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 oral solution should also be washed as soon as possible.

### Important information about some of the ingredients of this medicine

**Strattera 4 mg/ml Oral Solution** contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 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.
- The medicine should usually be taken 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 or your child are taking **Strattera 4 mg/ml Oral Solution** once a day and you or your child experience sleepiness or feel sick, your doctor may change your treatment schedule to twice a day.
- The medicine can be taken either with or without food.
- The oral solution should not be mixed in food or water as this can decrease the amount taken or make the taste less pleasant.
- Taking the medicine at the same time each day may help you remember to take it.

**Strattera 4 mg/ml Oral Solution** is available in a bottle. This is part of a pack which also includes a dosing device containing a 10 ml oral syringe marked in 1 ml increments and a press-in-bottle adaptor.
Ensure that the adaptor is fully inserted into the bottleneck before use.
Read the instructions for use booklet, which is included in the carton, for instructions on how to use the adaptor and the dosing syringe.

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

Long-term treatment:

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

**Do not exceed the recommended dose.**

**Tests and follow-up**

The doctor will perform several tests:

- Before beginning treatment - to ensure 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/your child have taken a higher dose,** contact your doctor or the nearest hospital Emergency Room immediately and bring the medicine package with you. Tell them how much medicine you have taken. The most commonly reported symptoms accompanying overdoses are gastrointestinal symptoms, sleepiness, dizziness, tremor, and abnormal behavior.

**If you forget to take this medicine** at the required time, you should take the dose as soon as you remember, 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 this medicine**
If you or your child stop taking **Strattera**, there are usually no side effects, but your ADHD symptoms may return. Contact your doctor before you or your child stop treatment.

- 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 or your child 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 4 mg/ml Oral Solution** 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. Your doctor will talk to you about these side effects.

Some side effects could be serious. **If you have any of the side effects below, contact your doctor immediately:**

**Uncommon side effects** (may affect 1-10 in 1,000 people):

- feeling or having a very fast heartbeat, abnormal rhythms of the heart
- suicidal thoughts

- 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:**

- suicidal thoughts (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

**You should stop taking Strattera and call your doctor immediately if you have any of the following side effects:**

- 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

**Other side effects reported are included in the following table. 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<br>- stomach pain<br>- decreased appetite (not feeling hungry)<br>- nausea or vomiting<br>- sleepiness<br>- increased blood pressure<br>- increased heart rate (pulse)<br><br>These side effects may disappear after a while in most patients. | - nausea<br>- dry mouth<br>- headache<br>- decreased appetite (not feeling hungry)<br>- problems getting to sleep, staying asleep and waking early<br>- increased blood pressure<br>- 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<br>- problems sleeping including waking early<br>- depression<br>- feeling sad or hopeless<br>- feeling anxious<br>- tics<br>- large pupils (the dark center of the eye)<br>- dizziness<br>- constipation<br>- loss of appetite<br>- upset stomach, indigestion<br>- swollen, reddened and itchy skin<br>- rash<br>- feeling lazy (lethargy)<br>- chest pain<br>- tiredness<br>- weight loss | - feeling agitated<br>- decreased interest in sex<br>- sleep disturbance<br>- depression<br>- feeling sad or hopeless<br>- feeling anxious<br>- dizziness<br>- an abnormal taste or change in taste that will not go away<br>- tremor<br>- tingling or numbness in the hands or feet<br>- sleepiness, drowsy, feeling tired<br>- constipation<br>- stomach ache<br>- indigestion<br>- wind (flatulence)<br>- vomiting<br>- hot flush or flushing |

| | |
|---|---|
| | - feeling or having a very fast heartbeat<br>- swollen, reddened and itchy skin<br>- increased sweating<br>- rash<br>- difficulty urinating, frequent or hesitant urination, pain during urination<br>- inflammation of the prostate gland (prostatitis)<br>- groin pain in men<br>- failure to obtain an erection<br>- retarded orgasm<br>- difficulty maintaining an erection<br>- menstrual cramps<br>- lack of strength or energy<br>- tiredness<br>- feeling lazy (lethargy)<br>- chills<br>- feeling irritable, jittery<br>- feeling thirsty<br>- weight loss |

| **Uncommon side effects** (may affect up to 1 in 100 people) | |
|---|---|
| **Children and young people over the age of 6** | **Adults** |
| - fainting<br>- tremor<br>- migraine<br>- blurred vision<br>- abnormal skin sensation, such as burning, prickling, itching, or tingling<br>- tingling or numbness in the hands or feet<br>- seizure (fits) | - restlessness<br>- tics<br>- fainting<br>- migraine<br>- blurred vision<br>- heart rhythm abnormal (QT prolongation)<br>- feeling cold in fingers and toes<br>- chest pain |

| | |
|---|---|
| - feeling or having a very fast heartbeat (QT prolongation)<br>- shortness of breath<br>- increased sweating<br>- itchy skin<br>- lack of strength or energy | - shortness of breath<br>- raised red itchy rashes (hives)<br>- muscle spasms<br>- an urge to urinate<br>- abnormal or absence of orgasm<br>- irregular menstruation<br>- 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)<br>- difficulty urinating, frequent or hesitant urination, pain during urination<br>- prolonged and painful erections<br>- groin pain in males | - poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease)<br>- 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 or your child 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffect
Medic@moh.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 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 bottle. The expiry date refers to the last day of that month.
- Do not store at a temperature above 30°C. Use within 45 days after the first time you open the bottle.
- Store in the original package.
- 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:**

Sodium benzoate, sodium dihydrogen phosphate dihydrate, phosphoric acid, liquid sorbitol, xylitol, artificial raspberry flavoring, sucralose, sodium hydroxide, purified water.

**What the medicine looks like and contents of the pack:**

**Strattera 4 mg/ml Oral Solution** is a clear colorless oral solution.

**Strattera 4 mg/ml Oral Solution** is available in a bottle with a child resistant cap containing 100 ml of solution. The pack also includes a dosing device consisting of a 10 ml oral syringe marked in 1 ml increments and a press-in-bottle adaptor.

**Strattera 4 mg/ml Oral Solution** is available in a multipack containing three bottles.

**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.

This leaflet was reviewed and approved by the Ministry of Health in June 2017, and was updated according to the Ministry of Health guidelines in May 2018.

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**Registration number of the medicine in the National Drug Registry of the Ministry of Health:**
158-61-35026-00.

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