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 4 mg/mL Oral Solution** 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 4 mg/mL Oral Solution**.

The risk of suicidal thoughts or suicide attempts is higher at the beginning of treatment and when changing the dose.
During treatment with **Strattera 4 mg/mL Oral Solution**, you must closely monitor your child's mood and behavior.
If any of the following symptoms appears, contact a doctor immediately:
anxiety, irritability, panic attack, sleep disorders, over excitement, hostility, aggressiveness, impulsiveness, 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 and section 2 "important information about some of the ingredients of this medicine".

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 for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

- **Strattera 4 mg/mL Oral Solution** contains atomoxetine and is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment program.
- In adults, **Strattera 4 mg/mL Oral Solution** is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) when the presence of symptoms of ADHD were pre-existing in childhood.

Therapeutic group: centrally acting sympathomimetics.

How the medicine works
Strattera 4 mg/mL Oral Solution increases the amount of noradrenaline in the brain. Noradrenaline is a chemical 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 starting the medicine for your symptoms to fully improve.

2. BEFORE USING THE MEDICINE

Do not use this medicine if you:

- are hypersensitive (allergic) to the active ingredient (atomoxetine hydrochloride) or 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 for depression and other mental-health problems. Taking **Strattera 4 mg/mL Oral Solution** 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 4 mg/mL Oral Solution** 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 4 mg/mL Oral Solution**.
- 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 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 4 mg/mL Oral Solution** 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 starting treatment with Strattera 4 mg/mL Oral Solution tell your doctor if you have:

- suicidal thoughts or attempted suicide.
- problems with your heart (including heart defects) or an increased heartbeat. **Strattera 4 mg/mL Oral Solution** can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects.
- high blood pressure. **Strattera 4 mg/mL Oral Solution** can increase blood pressure.
- low blood pressure. **Strattera 4 mg/mL Oral Solution** 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.
- aggressive feelings.
- unfriendly and angry (hostility) feelings.
- a history of epilepsy or have had seizures for any other reason. **Strattera 4 mg/mL Oral Solution** 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.

Before starting treatment with **Strattera 4 mg/mL Oral Solution**, tell your doctor or pharmacist if any of the above side effects applies to you. This is because **Strattera 4 mg/mL Oral Solution** can make these side effects worse. Your doctor will want to monitor how the medicine affects you.

Checks that your doctor will make before you start using this medicine:
These checks are to decide if **Strattera 4 mg/mL Oral Solution** is the correct medicine for you. Your doctor will measure your:
- blood pressure and your heart rate (pulse) before and during treatment with **Strattera 4 mg/mL Oral Solution**.
- height and weight if you are a child or teenager during treatment with **Strattera 4 mg/mL Oral Solution**.

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 4 mg/mL Oral Solution** is the correct medicine for you. Your doctor may decide that other medical tests are needed before you start taking this medicine.

Children and adolescents
The medicine is indicated for adults, adolescents and children over the age of 6.

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 4 mg/mL Oral Solution** 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 4 mg/mL Oral Solution** with medicines called MAOIs (monoamine oxidase inhibitors) used for depression. See section 2 “Do not use this medicine”.

If you are taking other medicines, **Strattera 4 mg/mL Oral Solution** 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 4 mg/mL Oral Solution**:
- 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 any of these medicines.
- some medicines used to treat mental health conditions.
- medicines that are known to increase the risk of seizures.

- some medicines that cause **Strattera 4 mg/mL Oral Solution** 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 4 mg/mL Oral Solution**:
- 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 4 mg/mL Oral Solution**.

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,
- 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 4 mg/mL Oral Solution**. You should be careful if you are driving a car or operating hazardous machinery until you know how **Strattera 4 mg/mL Oral Solution** affects you. If you feel tired, sleepy or dizzy you should not drive or operate machinery. 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 32.97 mg sorbitol in each mL. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

This medicine contains 2.64 mg of sodium (main component of cooking/table salt) in each mL. This is equivalent to 3.3% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 0.8 mg of sodium benzoate in each mL.

This medicine contains 9.8 mg of propylene glycol in each mL.

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 medicine.
- 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 are taking **Strattera 4 mg/mL Oral Solution** once a day and 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.

Do not exceed the recommended dose.

If you have taken accidently 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 stop taking **Strattera 4 mg/mL Oral Solution**, there are usually no side effects, but your ADHD symptoms may return. You should talk to your doctor first before you stop treatment.

Tests and follow-up during treatment with this medicine
Your doctor will do some tests:
- before you start treatment – to make sure that **Strattera 4 mg/mL Oral Solution** is safe and will be of benefit.
- after you start treatment – they will be done at least every 6 months, but possibly more often.

Tests will also be done 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 got worse while taking **Strattera 4 mg/mL Oral Solution**.

Long-term treatment
Strattera 4 mg/mL Oral Solution does not need to be taken for ever. If you take **Strattera 4 mg/mL Oral Solution** 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 <u>each time</u> you take your medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. <u>SIDE EFFECTS</u>
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 up to 1 in 100 people):
- feeling or having a very fast heartbeat, abnormal rhythms of the heart
- suicidal thoughts or feelings
- 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 the age of 18 have an increased risk of side effects such as:
- suicidal thoughts or feelings (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 4 mg/mL Oral Solution 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 - 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 - involuntary muscle cramps (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 such as not be able to urinate, 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	- restlessness

- migraine - blurred vision - abnormal skin sensation, such as burning, prickling, itching, or tingling - 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	- involuntary muscle cramps (tics) - fainting - migraine - blurred vision - heart rhythm abnormal (QT prolongation) - feeling cold in fingers and toes - chest pain - shortness of breath - raised red itchy rashes (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 such as 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 4 mg/mL Oral Solution**.
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 4 mg/mL Oral Solution** 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://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 is stated on the carton and bottle. The expiry date refers to the last day of that month.
Do not store at a temperature above 30ºC. 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:
Xylitol; sorbitol (E420), liquid (crystallising); sodium dihydrogen phosphate dihydrate; artificial raspberry flavor (containing propylene glycol (E1520)); sucralose; phosphoric acid, dilute; sodium benzoate (E211); 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.

Revised in April 2021 according to MOHs guidelines.

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

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