

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Strattera 10, 25 and 40 mg hard capsules**

**Atomoxetine**

**Important things you need to know about your medicine**

**This medicine is used to treat ADHD**

- The full name for ADHD is „Attention Deficit Hyperactivity Disorder“ .
- The medicine helps with your brain activity. It can help improve your attention, help you concentrate, and make you less impulsive.
- You need to have other help for ADHD as well as this medicine.

**Read Section 1 for more information.**

**Before you take this medicine, talk to your doctor if you:**

- have mental health problems
- have a problem with your heart or blood circulation
- have serious problems with the blood vessels in your brain such as a stroke.

**Read Section 2 for more information.**

**While taking this medicine:**

- See your doctor regularly. 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 you take it for more than a year.
- The most common side effects in children and young people are: headache, stomach ache, not feeling hungry, feeling or being sick, feeling sleepy, increased blood pressure, increased heart rate (pulse)
- The most common side effects in adults are: feeling sick, dry mouth, headache, not feeling hungry, not being able to sleep, increased blood pressure, increased heart rate (pulse)

**Read Sections 3 and 4 for more information.**

**Talk to your doctor straight away if any of the following happen:**

- your mood and how you feel changes
- you feel any problems with your heart e.g a fast or unusual heartbeat rhythm

**Read Section 2 and 4 for more information.**

**The rest of this leaflet includes more detail and other important information on the safe and effective use of this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.
- It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

**The leaflet has been written in sections:**

Sections 1 to 6 are for parents and carers (sometimes called „your guardians“ ). The last section is a special section for a child or young person to read.

However, all sections are written as though the child or young person taking the medicine is reading them.

**What is in this leaflet:**

1. What Strattera is and what it is used for
2. What you need to know before you take Strattera
3. How to take Strattera
4. Possible side effects
5. How to store Strattera
6. Contents of the pack and other information

**1. WHAT STRATTERA IS AND WHAT IT IS USED FOR**

**What it is used for**

Strattera contains atomoxetine and is used to treat attention-deficit and hyperactivity disorder (ADHD). It is used

- in children over six years of age
- in 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 it 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.

**About ADHD**

Children and young people with ADHD find it:

- hard to sit still and
- hard to concentrate.

It is not their fault that they cannot do these things. Many children and young people struggle to do these things. However, with ADHD they can cause problems with everyday life. Children and young people with ADHD may have difficulty learning and doing homework. They find it hard to behave well at home, at school or in other places. ADHD does not affect the intelligence of a child or young person. Adults with ADHD find it difficult to do all the things that children find difficult however this may mean they have problems with:

- Work
- Relationships
- Low self esteem
- Difficulties in education

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE STRATTERA**

**Do not take Strattera**

- 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. An 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 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 narrow or blocked blood vessels
- if you have a tumour of your adrenal gland (pheochromocytoma)

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.

**Warnings and Precautions**

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 behaviour) and agitation.
- 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.

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.

**Checks that your doctor will make before you start to take Strattera**

These checks are to decide if Strattera is the correct medicine for you.

Your doctor will measure your

- blood pressure and your heart rate (pulse) before and during the time you take Strattera
- your height and weight if you are a child or teenager during the time you take 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.

**Other medicines and Strattera**

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. 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 buy any of these products
- 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 in any doubt about whether any medicines you are taking are included in the list above, ask your doctor or pharmacist before taking Strattera.

**Pregnancy, breast-feeding and fertility**

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 breastfeeding or discontinue breastfeeding.

If you:

- are pregnant or breast feeding,
- think you may be pregnant or are planning to have a baby,
- planning to breastfeed your baby

Ask your doctor or pharmacist for advice before taking Strattera.

**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 heavy machinery until you know how Strattera affects you. If you feel tired, sleepy or dizzy you should not drive or 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.

**3. HOW TO TAKE STRATTERA**

- 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 when you take the medicine 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 remember to take it

**How much to take**

**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 1.2mg per kilogram of body weight daily.
- Body weight over 70kg: a starting 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 daily. 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.

**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 behaviour.

## If you forget 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 forgotten doses.

## If you stop taking Strattera

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.

## Things your doctor will do when you are on treatment

### Your doctor will do some tests

- before you start - to make sure that Strattera is safe and will be of benefit.
  - after you start - they will be done at least every 6 months, but possibly more often.
- They 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.

## 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 have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Strattera can cause side effects, although not everybody gets them. Although some people get side effects most people find that Strattera helps 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, see a doctor straight away.**

### Uncommon (affects 1 in 1,000)

- feeling or having a very fast heartbeat, abnormal rhythms of the heart
- thinking about or feeling like killing yourself
- 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 aged under 18 have an increased risk (affects less than 1 in 100 people) of side effects such as:

- thinking about or feeling like killing yourself
- mood swings or mood changes

### Adults have a reduced risk (affects less than 1 in 1000 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

### Very rarely (affects less than 1 in 10,000 people)

- liver injury

### You should stop taking Strattera and call 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 flu

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

Very Common side effects (affects more than 1 in 100 people)	
CHILDREN and YOUNG PEOPLE over 6 years	ADULTS
<ul style="list-style-type: none"><li>- headache</li><li>- pain in the stomach</li><li>- decreased appetite (not feeling hungry)</li><li>- feeling sick</li><li>- being sick</li><li>- sleepiness</li><li>- increased blood pressure</li><li>- increased heart rate (pulse)</li></ul>	<ul style="list-style-type: none"><li>- Feeling sick</li><li>- Dry mouth</li><li>- Headache</li><li>- Decreased appetite (not feeling hungry)</li><li>- Problems getting to sleep, staying asleep and waking early</li><li>- Increased blood pressure</li><li>- Increased heart rate (pulse)</li></ul>
These effects may disappear after a while in most patients.	

Common side effects (affects less than 1 in 10 people)	
CHILDREN and YOUNG PEOPLE over 6 years	ADULTS
<ul style="list-style-type: none"><li>- Being irritable or agitated</li><li>- Problems sleeping including waking early</li><li>- Depression</li><li>- Feeling sad or hopeless</li><li>- Feeling anxious</li><li>- Tics</li><li>- Large pupils (the dark centre of the eye)</li><li>- Dizziness</li><li>- Constipation</li><li>- Upset stomach, indigestion</li><li>- Swollen, reddened and itchy skin</li><li>- Rash</li><li>- Feeling lazy (lethargy)</li><li>- Tiredness</li><li>- Weight loss</li></ul>	<ul style="list-style-type: none"><li>- Feeling agitated</li><li>- Decreased interest in sex</li><li>- Sleep disturbance</li><li>- Depression</li><li>- Feeling sad or hopeless</li><li>- Feeling anxious</li><li>- Dizziness</li><li>- An abnormal taste or change in taste that will not go away</li><li>- Tremor</li><li>- Tingling or numbness in the hands or feet</li><li>- Sleepiness, drowsy, feeling tired</li><li>- Constipation</li><li>- Stomach ache</li><li>- Indigestion</li><li>- Wind (flatulence)</li><li>- Being sick</li><li>- Hot flush or flushing</li><li>- Feeling or having a very fast heartbeat</li><li>- Swollen, reddened and itchy skin</li><li>- Increased sweating</li><li>- Rash</li><li>- Problems going to the toilet such as not be able to urinate, frequent or hesitant</li></ul>

	<ul style="list-style-type: none"><li>- urinating, pain on urinating</li><li>- Inflammation of the prostate gland (prostatitis)</li><li>- Groin pain in men</li><li>- Failure to obtain an erection</li><li>- Menstrual cramps</li><li>- Lack of strength or energy</li><li>- Tiredness</li><li>- Feeling lazy (lethargy)</li><li>- Chills</li><li>- Feeling, irritable, jittery</li><li>- Feeling thirsty</li><li>- Weight loss</li></ul>
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Uncommon side effects (affects less than 1 in 100 people)	
CHILDREN and YOUNG PEOPLE over 6 years	ADULTS
<ul style="list-style-type: none"><li>- Fainting</li><li>- Tremor</li><li>- Migraine</li><li>- Abnormal skin sensation, such as burning, prickling, itching, or tingling</li><li>- Tingling or numbness in the hands or feet</li><li>- Seizure (fits)</li><li>- Feeling or having a very fast heartbeat (QT prolongation)</li><li>- Increased sweating</li><li>- Itchy skin</li><li>- Lack of strength or energy</li></ul>	<ul style="list-style-type: none"><li>- Restlessness</li><li>- Tics</li><li>- Fainting</li><li>- Migraine</li><li>- Tingling or numbness in the hands or feet</li><li>- Heart rhythm abnormal (QT prolongation)</li><li>- Feeling cold in fingers or toes</li><li>- Raised red itchy rashes (hives)</li><li>- Muscle spasms</li><li>- An urge to urinate</li><li>- Abnormal or absence of orgasm</li><li>- Irregular menstruation</li><li>- Ejaculation failure</li></ul>

Rare side effects (affects less than 1 in 1000 people)	
CHILDREN and YOUNG PEOPLE over 6 years	ADULTS
<ul style="list-style-type: none"><li>- Poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease)</li><li>- Problems going to the toilet such as frequent or hesitant urinating, pain on urinating</li><li>- Prolonged and painful erections</li><li>- Groin pain in males</li></ul>	<ul style="list-style-type: none"><li>- Poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease)</li><li>- Prolonged and painful erections</li></ul>

## 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.

## Reporting of side effects

Please tell your doctor or pharmacist if:

- You get any of these side effects and they become troublesome or get worse
- You notice any side effects not mentioned in this leaflet

You can also report side effects directly via UK: [www.mhra.co.uk/yellowcard](http://www.mhra.co.uk/yellowcard), Ireland: [www.imb.ie](http://www.imb.ie) or Malta: [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to Store Strattera

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the carton and blister after 'EXP'. The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions.

Medicines should be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Strattera 10, 25 and 40mg hard capsules contain

- The active substance is atomoxetine hydrochloride. Each hard capsule contains atomoxetine hydrochloride equivalent to 10mg, 25mg or 40mg of atomoxetine.
- The other ingredients are pregelatinised starch and dimeticone.
- The capsule shells contain sodium laurilsulphate and gelatin. The capsule shell colourants are:
  - Titanium dioxide E171 (10mg, 25mg and 40mg)
  - FD&C blue 2 (indigo carmine) E132 (25mg and 40mg)
  - Edible black ink (containing shellac and black iron oxide E172)

### What Strattera looks like and contents of the pack

Capsule, hard, 10mg (white, imprinted Lilly 3227/10 mg)

Capsule, hard, 25mg (blue/white, imprinted Lilly 3228/25 mg)

Capsule, hard, 40mg (blue, imprinted Lilly 3229/40 mg)

Strattera capsules are available in packs of 28 capsules.

### Product procured from within the EU and repackaged by the PPA holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

### Parallel Product Authorisation Number:

PPA 465/325/1

PPA 465/325/2

PPA/465/325/3

### Manufacturers:

Lilly S.A., Avda. De la Industria 30, 28108, Alcobendas, Madrid, Spain

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