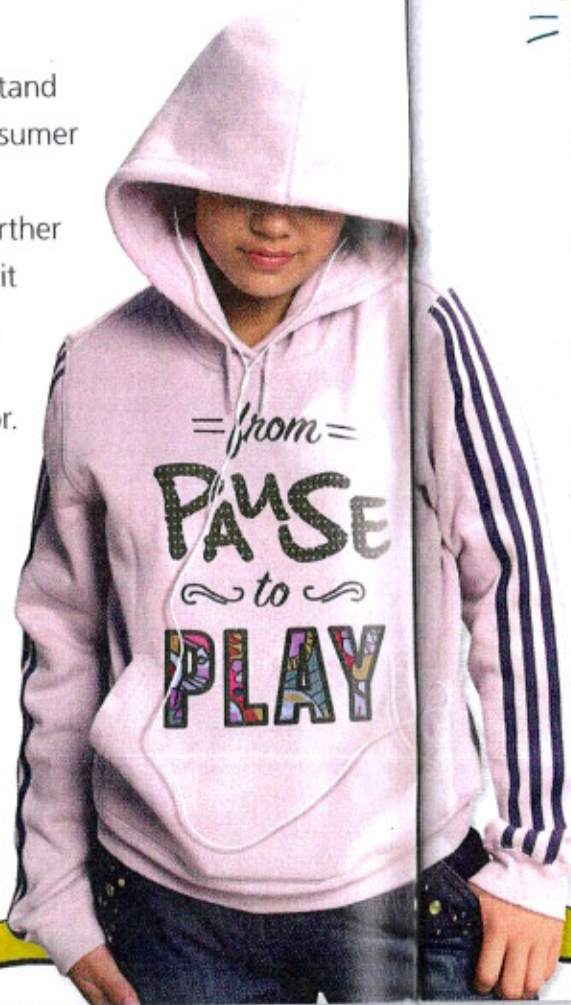


TUNE
IN TO
LIFE

Getting started on Strattera

This information is a guide to help you understand Strattera. It is not intended to replace the Consumer Medicine Information or the advice of your healthcare professional. Should you require further information about Strattera or Attention Deficit Hyperactivity Disorder (ADHD), please refer to the Consumer Medicine Information towards the end of this booklet, or contact your doctor.



CONTENTS

- ➔ Why do I need Strattera?
- ➔ How does Strattera work differently from stimulants?
- ➔ Tips for taking Strattera
- ➔ Things to look out for
- ➔ What can I do to help myself?



WHY DO I NEED STRATTERA?

STRATTERA TREATS YOUR ADHD DIFFERENTLY.^{1,3}

Your doctor has changed your medication to Strattera to help treat your ADHD. If you think you're the only one affected, think again. Australian statistics tell us that approximately 1-3 students in a classroom of 30 children/adolescents will have ADHD.⁴ It's a medical condition, so it's not your fault. You were born with ADHD, but you don't have to let it rule you.

IS THIS ME?

ADHD has recognisable symptoms, which is how your doctor made his or her diagnosis. You might recognise some of them:⁵

- * Trouble paying attention to detail
- * Problems getting started on a project or task, and I have problems finishing it
- * Blurting out what's on my mind and I don't listen well
- * Talking a lot and I'm restless

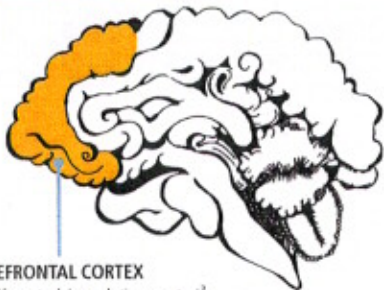
STRATTERA IS A MEDICINE DESIGNED TO TREAT THE SYMPTOMS OF ADHD WHICH COULD HELP YOU FIT IN BETTER.⁵

As you know, ADHD makes it pretty hard to focus on school or university, work and private life. And it's hard enough trying to make friends and get along with your parents, carers, teachers, brothers and sisters, without having to cope with ADHD as well. That's why your doctor thinks Strattera might help.⁵

HOW DOES STRATTERA WORK DIFFERENTLY FROM STIMULANTS?

Strattera acts on noradrenaline (NA) pathways^{1,2}

Strattera works on the **prefrontal cortex**, which is where we believe the main problems for ADHD occur.

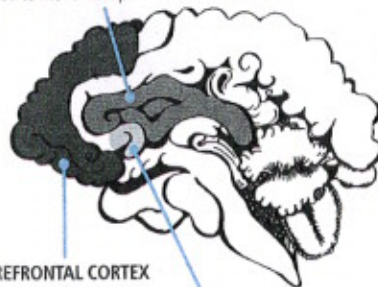


PREFRONTAL CORTEX
'Self control / regulation centre'²
Helps you to manage your **attention**,
behaviour and emotions.²

Stimulants act on dopamine (DA) pathways^{1,3}

Stimulants also affect the **striatum** and the **nucleus accumbens** as well as the prefrontal cortex.

STRIATUM 'Motor centre'
Linked to movement problems such as **tics**.¹



PREFRONTAL CORTEX
NUCLEUS ACCUMBENS 'Reward centre'¹
Linked to potential **drug abuse problems**.¹

- ⇒ Stimulants are used as a first line treatment for ADHD, however this therapy may not be suitable for everyone^{1,6}
- ⇒ Strattera is available to people who need another treatment option due to side effects or contraindications to the stimulants⁴
- ⇒ Strattera works differently from stimulants^{1,3}
- ⇒ It acts on a chemical in the front part of the brain that controls attention, behaviour and emotion⁷
- ⇒ Strattera starts to improve symptoms gradually⁷

WHAT DIFFERENCES WILL I SEE?

With Strattera, you may notice you are more focussed at school, and find it easier getting ready in the morning and completing tasks.^{3,8}

You may feel less angry and upset, and get along more with your family and friends.⁹



WHAT DOES IT MEAN FOR ME?

Your doctor is likely to start you on a low dose of Strattera at first, to give your body a chance to get used to it. Then, over time, your dose will be increased until you reach the dose that works best for you.⁹

- ✓ Strattera improves the symptoms of your ADHD, and will continue to improve them over time⁷
- ✓ There is very little risk of addiction with Strattera⁸
- ✓ It can take around 6-9 weeks to feel the full effects of Strattera⁹
- ✓ If you experience any side effects, they should be mild to moderate⁷

STRATTERA CAN PROVIDE 24-HOUR COVERAGE.¹⁰



TIPS FOR TAKING STRATTERA

- ☑ Take Strattera at around the same time every day⁷
- ☑ If you miss a dose, take it as soon as possible¹¹
- ☑ Do not take a larger dose than has been prescribed¹¹
- ☑ Capsules should not be opened⁷
- ☑ You can take Strattera with or without food – food might help to reduce any nausea you might experience^{7,10}
- ☑ If you have any concerns, talk to your doctor

PLEASE USE YOUR PROGRESS TRACKER IN THE BACK OF THE BOOKLET TO SEE HOW YOU ARE GETTING ON WITH STRATTERA.



THINGS TO LOOK OUT FOR

Like all medicines, Strattera might cause side effects in some people. Here are the most common ones:"

- * Reduced appetite. Somehow, your favourite burgers just don't appeal any more
- * Diarrhoea, stomach pain or constipation
- * Nausea or vomiting. You might feel sick or throw up
- * Dizziness. You might feel light-headed
- * Tiredness. Okay, we all feel tired, but you might feel sleepy during the day, or wake up way too early in the mornings
- * Mood swings. Your mood might be up and down, or you might be more irritable than usual

If you experience any side effects, they should be mild to moderate. You need to keep taking Strattera every day for it to work, so if you do have side effects, it's important that you **KEEP TAKING YOUR MEDICINE** – don't just stop abruptly. Go and see your doctor for advice to help you.

WHAT CAN I DO TO HELP MYSELF?

- ✓ Tell your parents or carers about any symptoms or feelings that might be due to your new medicine. You might need to see your doctor to discuss it
- ✓ Upset stomach? You might find it helps if you take Strattera with food"
- ✓ If you're feeling tired during the day, you can try taking Strattera at a different time of day – ask your doctor about changing your regular time
- ✓ If you **EVER** feel like life's not worth living, tell your parents or carers **IMMEDIATELY**. Thoughts like these might be due to your medicine. Things can be done to help you feel better about yourself and life in general



HOW CAN I MAKE SURE ADHD DOESN'T AFFECT MY LIFE?

As well as taking Strattera, there are things you can do to help make sure ADHD doesn't mess up your everyday life. Here are a few tips to get you started on the road to a new you:

Get organised

Keep a checklist of things you need to do each day or week. Colour-coding can help you organise your tasks.¹²

Stick to a routine (as much as you can)

Life can be chaotic at the best of times, so make things easy on yourself by trying to get into a routine as much as possible.¹²

Plan ahead

Pick out your clothes the night before. That way, you're less likely to forget things in the morning.¹²

Rest up

Tiredness and fatigue can make ADHD feel worse, so make sure you get plenty of rest.¹²

Let people in

Your parents or carers, your brothers and sisters, your friends, your teachers, and ADHD support groups around the country are all there to help you, if you let them.¹²



MY RECOMMENDED DOSE

Weight:	
Starting dose:	Target dose:
Week 1 dose:	
Week 2 dose:	
Week 3 dose:	
Week 4 dose:	
Week 8 dose:	

MY PROGRESS ON STRATTERA

- * It's important to recognise your symptoms and monitor your progress
- * Be aware of how you're feeling and note changes
- * This will make it easier for your doctor to help you with your symptoms



At your first appointment, mark any tasks you find particularly challenging with a (X). For each follow-up appointment, rate each task based on: (✓) slight improvement, (✓✓) moderate improvement or (✓✓✓) great improvement.

	Week 1	Week 2	Week 3	Week 4	Week 8	Week 12
Date:						
Getting on with my day						
Waking up / getting to sleep easier						
Being more organised						
Better at getting ready for school						
Staying on track in class						
Better at sports and hobbies						
Finishing assignments						
Doing chores						
Getting on with others						
Getting on well with my: Family						
Classmates						
Teachers						
Positively participating in family activities						
Feeling like I fit in better						
About me						
Feeling better about myself						
Not getting upset as easily						
Not getting angry as easily						
Not overacting as easily						
Able to get over things quickly						
Not forgetting stuff as much						

STRATTERA® atomoxetine hydrochloride

Consumer Medicine Information STRATTERA® Published by MIMS/myDr August 2013 1

What is in this leaflet?

This leaflet answers some common questions about STRATTERA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. The information in this leaflet was last updated on the date shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.lilly.com.au. The updated leaflet may contain important information about STRATTERA and its use that you should be aware of. All medicines have risks and benefits. Your doctor has weighed the risks of you taking STRATTERA against the benefits it may have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

What STRATTERA is used for

STRATTERA is used to treat Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years and older, adolescents and adults. ADHD is a behavioural disorder that causes lack of focus and/or hyperactivity that is much more frequent or severe than others who are close in age or development.

STRATTERA works by acting on brain chemicals called amines which are involved in controlling behaviour.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Available evidence suggests that STRATTERA does not have a significant potential for abuse. This medicine is available only with a doctor's prescription.

Before you take STRATTERA

When you must not take it

Do not take STRATTERA if you have an allergy to:

- any medicine containing atomoxetine hydrochloride (the active ingredient in STRATTERA)
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take STRATTERA if you have any of the following conditions:

- certain heart diseases such as moderate to severe hypertension, abnormal or dangerously fast heart beat, thickening and hardening of the walls of the arteries due to cholesterol deposits
- an uncontrolled overactive thyroid gland which causes increased appetite, weight loss, intolerance to heat, increased sweating, tremors, and rapid heart rate
- a tumour of the adrenal gland, which sits near the kidney. The symptoms are bouts of anxiety and headaches, palpitations, dizziness, a feeling of weakness, nausea, vomiting, diarrhoea, dilated pupils and blurring vision, stomach pains, and raised blood pressure

Do not take STRATTERA if you are taking medicine called a monoamine oxidase inhibitor (MAOI) for the treatment of depression or have been taking a MAOI within the last 14 days.

Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI. If you do take STRATTERA while you are taking a MAOI, you may experience shaking (tremor), shivering, muscle stiffness, fever, rapid pulse, rapid breathing or confusion.

Do not take STRATTERA if you have high pressure in the eye (glaucoma), or have a family history of glaucoma.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- high blood pressure
- low blood pressure
- fast heart beat
- heart disease
- conditions affecting blood flow in the brain, such as stroke
- liver disease
- kidney disease
- an overactive thyroid gland
- enlargement or disease of the prostate
- difficulty passing urine
- seizures, fits or convulsions
- any psychiatric disorder, including depression or bipolar disorder

Tell your doctor if you or your child have or have had:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts at self-harm

You may wish to see a paediatric psychiatrist for further assessment and supervision of your child.

Tell your doctor if you:

- are involved in strenuous exercise or activities
- are using a group of medicines called stimulants
- have a family history of sudden/cardiac death

STRATTERA generally should not be used in children, adolescents or adults with known structural heart abnormalities.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved. Safety and effectiveness in elderly patients older than 65 years and children younger than 6 years have not been established.

If you have not told your doctor about any of the above, tell him/her before you start taking STRATTERA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by STRATTERA or may affect how it works. You may need different amounts of your medicines or you may need to take different medicines. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression. **You should stop taking MAOIs at least two weeks before starting STRATTERA**
- certain medicines used to treat depression such as fluoxetine, paroxetine, desipramine, imipramine, venlafaxine and mirtazapine
- certain medicines used to treat irregular heart beat such as quinidine
- medicines used to treat low blood pressure or to raise blood pressure (pressor agents)
- medicines containing the decongestants pseudoephedrine or phenylephrine
- asthma reliever medicines such as salbutamol, when taken orally as a syrup or as an injection
- certain medicines taken for anxiety such as diazepam or to treat epilepsy such as phenytoin

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking STRATTERA.

How to take STRATTERA

Carefully follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

For children and adolescents up to 70 kg body weight, the usual starting dose is approximately 0.5 mg/kg once a day. After a minimum of 3 days, if necessary, the dose may be increased to approximately 1.2 mg/kg once daily in the morning or as evenly divided doses in the morning and late afternoon/early evening. After 2 to 4 additional weeks, if necessary, the dose may be increased to a maximum of 1.4 mg/kg once daily or 100 mg. For children and adolescents greater than 70 kg body weight and adults, the usual starting dose is 40 mg once a day. After a minimum of 3 days, if necessary, the dose may be increased to approximately 80 mg once daily in the morning or as evenly divided doses in the morning and late afternoon/early evening.

After 2 to 4 additional weeks, the dose may be increased to a maximum of 100 mg. If therapy is interrupted for more than 1 week, treatment should be started at the lowest recommended dose. Your doctor will tell you how much STRATTERA you need to take each day. Your doctor may increase or decrease your dose depending on your condition and any other illness that you may have.

How to take it

Swallow the capsules whole with a full glass of water. STRATTERA can be taken with or without food.

When to take it

STRATTERA is usually taken one or two times a day (early morning and late afternoon/early evening). **If you find that you are sleepy during the day or have trouble sleeping at night, talk to your doctor about the best time to take your medicine. Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it. It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally. Do not take more than your total daily dose in a 24 hour period. If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

If you think that you or anyone else may have taken too much STRATTERA, immediately telephone your doctor or the Poisons Information Centre (telephone Australia: 13 11 26, NZ: 0800 POISON or 0800 764 766) for advice, or go to Emergency Department at the nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. If you have taken too much STRATTERA, the most common signs are sleepiness, agitation, hyperactivity, unusual behaviour and an upset stomach. In some cases of overdose, seizures have been reported.

While you are taking STRATTERA

Things you must do

Contact your doctor or a paediatric psychiatrist straight away or go to the nearest hospital for treatment if you notice any sudden change in your child's behaviour, if your child is demonstrating any of the following warning signs, if you notice any of the following or if they seem worse.

Signs to watch for:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- difficulty sleeping (insomnia)
- new or worse irritability

- acting on dangerous impulses
- an extreme increase in activity and talking
- other unusual changes in behaviour

Preventing suicidal thoughts or action

To try and prevent suicidal thoughts or actions in your child, talk with and listen to your child about his or her thoughts and feelings and pay close attention to changes in his or her moods or action, especially if the changes occur suddenly. Other important people in your child's life can help by paying attention as well (e.g. brothers and sisters, teachers, caregivers and other important people). Pay close attention to your child whenever STRATTERA is started or its dose is changed (See Side Effects).

If you notice an increase in aggression or hostility since taking this medication, you should call your doctor as soon as possible. Tell your doctor if you experience a seizure, fit or convulsion. If you already suffer from seizures, fits or convulsions, tell your doctor if they seem to increase in frequency. Tell your doctor if you notice changes in your sexual function while you are taking this medicine. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking STRATTERA. Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery. If you become pregnant while taking this medicine, tell your doctor immediately. Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests (blood pressure and heart rate) from time to time while on therapy. After starting STRATTERA children may have a reduced rate of growth so your doctor may also monitor your height and weight from time to time when on long term therapy.

Things you must not do

Do not take STRATTERA to treat any other complaints unless your doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you. Do not open your STRATTERA capsules as the content is an eye irritant. In the event of capsule content coming in contact with the eye, flush the affected eye immediately with water and seek medical advice. Hands and any potentially contaminated surfaces should be washed as soon as possible.

Things to be careful of

Be careful driving or operating machinery until you know how STRATTERA affects you. This medicine may cause dizziness, tiredness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. **If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.** Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

If your doctor advises you to stop taking STRATTERA, do not take monoamine oxidase inhibitors (MAOIs) within the first two weeks after stopping STRATTERA.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking STRATTERA. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor or pharmacist if you notice any of the following:

Children and adolescents:

- constipation
- upset or sore stomach, nausea, vomiting
- diarrhoea
- decreased appetite
- decreased weight
- headache
- dizziness
- constant flu like symptoms such as chills, fever, irritated watery eyes sore throat
- dilated pupils
- mood swings, irritability
- skin rash, redness, itching
- early morning waking, tiredness, difficulty sleeping
- unusual weakness
- lacking energy, feeling tired

Adults:

- dry mouth
- thirst
- difficulty urinating, abnormal, painful and/or frequent urination
- sexual problems
- testicular or genital pain in males
- painful or irregular menstrual periods
- hot flushes
- increased sweating
- tickling, tingling, burning, pricking, or numbness of skin
- feeling jittery, tremors
- agitation
- persistent abnormal taste

Tell your doctor immediately or go to the Emergency Department of your nearest hospital if you notice any of the following in you/your child while taking STRATTERA:

- fast or irregular heart beat
- fainting

- numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to cold
- seizures, fits or convulsions
- signs of liver injury such as dark urine, yellowing of the skin or eyes, severe cramps of the stomach, or unexplained nausea, fatigue, lethargy, itching or flu like symptoms
- episodes of overactivity, elation or irritability
- confusion or hallucinations (seeing or feeling things that are not really there)
- thoughts of suicide or attempts to harm yourself (also see Things You Must Do if you notice this behaviour in children or adolescents).

These are serious side effects, which may require medical attention. Serious side effects are rare or very rare. Other side effects not listed above may also occur in some people.

Tell your doctor or pharmacist if you notice any other effects.

After taking STRATTERA

Storage

Keep your capsules in the pack until it is time to take them. If you take the capsules out of the pack they may not keep as well.

Keep your capsules in a cool dry place where the temperature stays below 25°C. Do not store STRATTERA or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car. Heat and dampness can destroy some medicines. **Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

- STRATTERA 10 mg capsules are coloured opaque white and are marked with "Lilly", "3227" and "10 mg"
- STRATTERA 18 mg capsules are coloured gold and opaque white and are marked with "Lilly", "3238" and "18 mg"
- STRATTERA 25 mg capsules are coloured opaque blue and opaque white and are marked with "Lilly", "3228" and "25 mg"
- STRATTERA 40 mg capsules are coloured opaque blue and are marked with "Lilly", "3229" and "40 mg"
- STRATTERA 60 mg capsules are coloured opaque blue and gold and are marked with "Lilly", "3239" and "60 mg"
- STRATTERA 80 mg capsules are coloured opaque brown and opaque white and are marked with "Lilly", "3250" and "80 mg"
- STRATTERA 100 mg capsules are coloured opaque brown and are marked with "Lilly", "3251" and "100 mg"

Ingredients

STRATTERA contains 10, 18, 25, 40, 60, 80 or 100 mg of atomoxetine hydrochloride as the active ingredient. It also contains:

- starch (pregelatinised maize)
- dimethicone 350
- gelatin
- sodium lauryl sulfate
- edible black ink
- one or more of the following:
 - indigo carmine CI73015
 - iron oxide yellow CI77492
 - iron oxide red CI77491
 - titanium dioxide

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Supplied in Australia by:

Eli Lilly Australia Pty Limited

112 Wharf Road

WEST RYDE NSW 2114

Australian Registration Number:

- STRATTERA 10 mg capsules - AUST R 90592
- STRATTERA 18 mg capsules - AUST R 90593
- STRATTERA 25 mg capsules - AUST R 90594
- STRATTERA 40 mg capsules - AUST R 90595
- STRATTERA 60 mg capsules - AUST R 90596
- STRATTERA 80 mg capsules - AUST R 146333
- STRATTERA 100 mg capsules - AUST R 146413

Supplied in NZ by:

Eli Lilly and Company (NZ) Ltd.

Level 3, Axon House

414-422 Khyber Pass Road

Newmarket Auckland, New Zealand

This leaflet was revised in June 2013. ®=Registered Trademark. **References:** 1. Bymaster FP, et al. *Neuropsychology*. 2002; 27(5):699-11. 2. Arnsten AF, et al. *J Am Acad Child Adolesc Psychiatry*. 2012; 51(4):356-67. 3. Prince JB, et al. *J Clin Psychopharmacol*. 2008; 28:539-45. 4. Willcutt EG. *Neurotherapeutics*. 2012; 9(3):490-99. 5. Wehmeier PM, et al. *J Adolesc Health*. 2010; 46:209-17. 6. del Campo, et al. *Biol Psychiatry*. 2011; 69(12):e145-57. 7. Strattera Approved Product Information, 2013. 8. Wehmeier PM, et al. *Child Adolesc Psychiatry Ment Health*. 2009; 3(1):5. 9. Newcorn JH, et al. *J Am Acad Child Adolesc Psychiatry*. 2009; 48(5):511-18. 10. Block SL, et al. *Clin Paediatr*. 2009; 48(7):723-32. 11. Strattera CMI, May 2009. 12. Attention-deficit/hyperactivity disorder (ADHD) in children. Lifestyle and home remedies. www.mayoclinic.com/health/adhd/DS00275/DSECTION=lifestyle-and-home-remedies. Accessed February 2014.