PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

STRATTERA 10 mg (capsules)

STRATTERA 18 mg (capsules)

STRATTERA 25 mg (capsules)

STRATTERA 40 mg (capsules)

STRATTERA 60 mg (capsules)

STRATTERA 80 mg (capsules)

WARNING: SUICIDAL IDEATION IN CHILDREN AND ADOLESCENTS

STRATTERA (atomoxetine) increased the risk of suicidal ideation in children or adolescents.

Patients started on therapy should be closely monitored.

Each capsule contains **atomoxetine** hydrochloride equal to 10 mg, 18 mg, 25 mg, 40 mg, 60 mg or 80 mg atomoxetine.

Read all of this leaflet carefully before you or a child in your care start taking STRATTERA (Stra-TAIR-a)

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

- STRATTERA has been prescribed for you personally or a child in your care and you should not share this medicine with other people. It may harm them, even if their symptoms are the same as yours or a child in your care.

WHAT STRATTERA CONTAINS

The active substance is atomoxetine.

The other ingredients are black ink, dimethicone, FD&C blue 2 (25 mg, 40 mg and 60 mg only), gelatin, pregelatinised starch, red iron oxide (80 mg only), sodium laurilsulfate, titanium dioxide, yellow iron oxide (18 mg, 60 mg and 80 mg only).

LACTOSE FREE.

WHAT STRATTERA IS USED FOR

STRATTERA is used to treat Attention-Deficit/ Hyperactivity Disorder (ADHD) in children 6 years of age or older, adolescents and adults.

BEFORE YOU TAKE STRATTERA OR GIVE STRATTERA TO A CHILD IN YOUR CARE

Do not take or give STRATTERA to a child in your care if you or a child in your care:

- are allergic to atomoxetine or any of the other ingredients of STRATTERA~~;~~
- 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 even be life-threatening

- have an eye disease called narrow-angle glaucoma (increased pressure in your eye)
- have or had liver problems
- have a condition called pheochromocytoma (tumour of your adrenal gland)
- have uncontrolled high blood pressure
- have serious problems with your heart which may be affected by an increase in heart rate and or blood pressure.

Take special care with STRATTERA

Tell your doctor before taking or giving STRATTERA to a child in your care if you or a child in your care:

- have possible allergic reactions including severe allergic reactions known as anaphylaxis;
- have thoughts about killing yourself or trying to kill yourself
- have aggressive feelings
- have unfriendly and angry (hostility) feelings
- have or had liver problems;
- have different moods or feel very unhappy
- if your child is not growing or gaining weight as expected
- have high blood pressure. STRATTERA can increase blood pressure;
- have problems with your heart or an irregular heartbeat. STRATTERA can increase your heart rate (pulse);
- have low blood pressure. STRATTERA can cause dizziness or fainting in people with low blood pressure;
- have poor circulation which makes fingers and toes numb and pale (Raynauds disease)
- have problems with sudden changes in your blood pressure or heart rate
- have cardiovascular disease or past medical history of stroke
- have problems passing urine.

Taking STRATTERA with food and drink

STRATTERA may be taken with or without food.

Pregnancy and breastfeeding

If you think you might be pregnant or are pregnant, or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking STRATTERA.

The safety of STRATTERA during pregnancy and whilst breastfeeding has not been established.

If you are using STRATTERA you should not breastfeed your baby.

Driving and using machinery

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.

Taking other medicines with STRATTERA

Always tell your healthcare professional if you or a child in your care are taking any other medicines. (This includes complementary or traditional medicines.)

- Do not take STRATTERA with medicines called MAOIs (monoamine oxidase inhibitors) including linezolid.
- STRATTERA may change the way your body reacts to salbutamol (a medicine to treat asthma). If you are taking salbutamol by a nebuliser, aerosol, or by mouth (for example syrup or tablets), or having a salbutamol injection together with STRATTERA, you may feel as if your heart is racing.
- STRATTERA should be used with caution if you are taking medication to control high blood pressure.

HOW TO TAKE STRATTERA

Do not share medicines prescribed for you or a child in your care with any other person.

- Always take STRATTERA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- The usual dose is taken one or two times a day (morning and late afternoon or early evening).
- Your doctor will tell you how long your treatment with STRATTERA will last.
- The capsules should be swallowed whole.
- You can take STRATTERA 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 STRATTERA at the same time each day may help you remember to take it.
- Do not give STRATTERA to children under six years old.
- If you have the impression that the effect of STRATTERA is too strong or too weak, tell your doctor or pharmacist.

If you or a child in your care take more STRATTERA than should be taken:

The most commonly reported symptoms accompanying overdoses are gastrointestinal symptom, sleepiness, dizziness, tremor and abnormal behaviour. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. If possible, tell them how many capsules you have taken.

If you forget to take STRATTERA

If you (or a child in your care) misses 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 individual doses.

POSSIBLE SIDE EFFECTS

STRATTERA can have side effects.

Not all side effects reported for STRATTERA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking STRATTERA, please consult your doctor, pharmacist or other health care professional for advice.

You should stop taking or giving STRATTERA and call your doctor immediately if you or a child in your care have any of the following:

- serious allergic reaction with symptoms of
  - swelling of the face, lips, tongue and throat
  - difficulty breathing
  - hives (small raised, itchy patches of skin)
- dark urine
- yellow skin or yellow eyes
- Tummy pain which is sore when you press it (tenderness) on the right side just below the ribs
- a feeling of sickness (nausea) that is unexplained
- tiredness
- itching
- feeling that you are coming down with flu

If you or a child in your care have any of the side effects below, see a doctor straight away.

- 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

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

Children and adolescents over 6 years	**Adults**
• headache • pain in the stomach • decreased appetite (not feeling hungry) • feeling sick (nausea) • being sick (vomiting) • sleepiness • increased blood pressure • increased heart rate (pulse) • being irritable or agitated • problems sleeping including waking early • depression • large pupils (the dark centre of the eye) • dizziness • constipation • loss of appetite • upset stomach, indigestion	• feeling sick (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) • feeling agitated • decreased interest in sex • sleep disturbance • dizziness • an abnormal taste or change in taste that will not go away • tremor

• swollen, reddened and itchy skin • rash • tiredness • weight loss • mood swings	• tingling or numbness in the hands or feet • sleepiness, drowsy, feeling tired • constipation • stomach ache • indigestion • wind (flatulence) • being sick (vomiting) • hot flush or flushing • feeling or having a very fast heartbeat • increased sweating • rash • problems going to the toilet such as not be able to urinate, frequent or hesitant urinating, pain on urinating • inflammation of the prostate gland (prostatitis) • groin pain in men • failure to obtain an erection • difficulty maintaining an erection

	• menstrual cramps • painful menstruation • lack of strength or energy • tiredness • chills • feeling irritable, jittery • feeling thirsty • weight loss • ejaculation disorder

The following side effects have been less frequently reported:

Children and adolescents over 6 years	**Adults**
• fainting • tremor • blurred vision • feeling or having a very fast heartbeat (QT prolongation) • lack of strength or energy • problems going to the toilet such as frequent or hesitant urination	• restlessness • blurred vision • feeling cold in fingers and toes • raised red itchy rashes (hives) • muscle spasms • an urge to urinate • abnormal or absence of orgasm • irregular menstruation

• abnormal skin sensation such as burning, prickling, itching or tingling	• ejaculation failure • feeling cold • itchy skin • poor circulation which makes toes and fingers numb and pale (Raynaud's disease) • increased sweating • painful prolonged erection • fainting • tics • numbness • hallucinations • depressed mood • depression • feeling anxious

If you notice any side effects not mentioned in this leaflet please inform your doctor or pharmacist.

STORING AND DISPOSING OF STRATTERA

Store all medicines out of reach of children.

STRATTERA should be stored at or below 25 °C.

Do not use after the expiry date shown on the carton.

Keep in original packaging until required for use.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF STRATTERA

STRATTERA 10 mg capsules, PU3227, are supplied in opaque white or clear plastic web film and aluminium foil blister packs of 28.

STRATTERA 18 mg capsules, PU3238, are supplied in opaque white or clear plastic web film and aluminium foil blister packs of 28.

STRATTERA 25 mg capsules, PU3228, are supplied in opaque white or clear plastic web film and aluminium foil blister packs of 28.

STRATTERA 40 mg capsules, PU3229, are supplied in opaque white or clear plastic web film and aluminium foil blister packs of 28.

STRATTERA 60 mg capsules, PU3239, are supplied in opaque white or clear plastic web film and aluminium foil blister packs of 28.

STRATTERA 80 mg capsules, PU3250, are supplied in opaque white or clear plastic web film and aluminium foil blister packs of 28.

IDENTIFICATION OF STRATTERA

STRATTERA 10 mg (Capsule, size 3) has an opaque white body and opaque white cap and is imprinted with "Lilly 3227" and "10 mg" in black ink.

STRATTERA 18 mg (Capsule, size 3) has an opaque white body and gold cap and is imprinted with "Lilly 3238" and "18 mg" in black ink.

STRATTERA 25 mg (Capsule, size 3) has an opaque white body and opaque blue cap and is imprinted with "Lilly 3228" and "25 mg" in black ink.

STRATTERA 40 mg (Capsule, size 3) has an opaque blue body and opaque blue cap and is imprinted with "Lilly 3229" and "40 mg" in black ink.

STRATTERA 60 mg (Capsule, size 2) has a gold body and opaque blue cap and is imprinted with "Lilly 3239" and "60 mg" in black ink.

STRATTERA 80 mg (Capsule, size 2) has an opaque white body and opaque brown cap and is imprinted with "Lilly 3250" and "80 mg" in black ink.

REGISTRATION NUMBERS

STRATTERA 10 mg capsules: 38/1.2/0520

STRATTERA 18 mg capsules: 38/1.2/0521

STRATTERA 25 mg capsules: 38/1.2/0522

STRATTERA 40 mg capsules: 38/1.2/0523

STRATTERA 60 mg capsules: 38/1.2/0524

STRATTERA 80 mg capsules: 42/1.2/0789

NAME AND ADDRESS OF REGISTRATION HOLDER

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STRATTERA 10 mg , 18 mg , 25 mg, 40 mg , 60 mg: 03/06/2005

STRATTERA 80 mg: 05/08/2011

Date of the most recently revised approved patient information leaflet: 20 March 2018