



Applicant: Aurogen SA (Pty) Ltd

Product Name: STRADENT

Dosage form and strength: Capsule, 10 mg, 18 mg, 25 mg, 40 mg, 60 mg

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2020

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1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S5

PATIENT INFORMATION LEAFLET

STRADENT 10 mg

STRADENT 18 mg

STRADENT 25 mg

STRADENT 40 mg

STRADENT 60 mg

(Atomoxetine hydrochloride)

Sugar free

Read all of this leaflet carefully before you take

STRADENT

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other health care provider.
- **STRADENT** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What **STRADENT** is and what it is used for
2. What you need to know before you take **STRADENT**



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3. How to take **STRADENT**
4. Possible side effects
5. How to store **STRADENT**
6. Contents of the pack and other information
- 1. What STRADENT is and what it is used for**

STRADENT belongs to a group of medicines psychoanaleptics and is used to treat Attention-Deficit/ Hyperactivity Disorder (ADHD) in children 6 years of age or older, adolescents and adults

2. What you need to know before you take STRADENT or give STRADENT to a child in your care

Do not take STRADENT or give to a child in your care:

- If you are hypersensitive (allergic) to Atomoxetine hydrochloride or any of the ingredients of **STRADENT** (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 **STRADENT** 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.



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Warnings and precautions

WARNING: SUICIDAL IDEATION IN CHILDREN AND ADOLESCENTS

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

Patients started on therapy should be closely monitored.

Tell your doctor before taking or giving **STRADENT** 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
- feel elated or over-excited which causes unusual behaviour
- have false perceptions of reality
- have or had liver problems;
- have different moods or feel very unhappy
- start having seizures
- if your child is not growing or gaining weight as expected
- have high blood pressure. **STRADENT** can increase blood pressure;
- have problems with your heart or an irregular heartbeat.
STRADENT can increase your heart rate (pulse);
- have low blood pressure. **STRADENT** can cause



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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

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Children

STRADENT has not been studied in children under 6 years of age and therefore should not be used in this patient population.

Other medicine and **STRADENT**:



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Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

The use of **STRADENT** with these medicines may cause undesirable interactions.

- Do not take **STRADENT** with medicines called MAOIs (monoamine oxidase inhibitors) used for depression. (See section 2 “Do not take **STRADENT**”)

If you are taking other medicines, **STRADENT** 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 **STRADENT**:

- medicines that increase blood pressure, for example salbutamol or are used to control blood pressure, for example amlodipine felodipine
- 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, for example pseudoephedrine. It is important to check with your pharmacist when you get any of these products.
- some medicines used to treat mental health conditions, for example fluoxetine, paroxetine
- medicines that are known to increase the risk of seizures for example butyrophenone, mefloquine
- some medicines that cause **STRADENT** 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



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The medicines below may lead to an increased risk of an abnormal rhythm of the heart when taken with **STRADENT**:

- medicines used to control the rhythm of the heart, for example amiodarone, sotalol
- medicines which change the concentration of salts in the blood, for example hydrochlorothiazide
- medicines for malaria prevention and treatment (such as mefloquine)
- 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 **STRADENT**.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

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

If you are using **STRADENT** you should not breastfeed your baby.

Driving and using machines

STRADENT may make you feel tired, sleepy or dizzy. Do not drive or operate tools or machines if you experience such side effects.



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It is not always possible to predict to what extent **STRADENT** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **STRADENT** affects them.

3. How to take STRADENT

Do not share medicines prescribed for you with any other person. Always take **STRADENT** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The capsules should be swallowed whole.

The capsules should not be opened and the contents inside the capsules should not be removed and taken in any other way.

You can take **STRADENT** with or without food.

Taking **STRADENT** at the same time each day may help you remember to take it.

Do not give **STRADENT** to children under 6 years of age.

How much to take If you are a child or adolescent (6 years or older):

Your doctor will tell you how much **STRADENT** you should take and will calculate this according to your weight. Your doctor will normally start you on a lower dose before increasing the amount of **STRADENT** you need to take according to your body weight.

Body weight up to 70 kg:

A starting total daily dose of 0,5 mg per kg of body weight for a minimum of 7 days. Your doctor may then decide to increase this to the usual maintenance dose of about 1,2 mg per kg of body weight daily.



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Body weight over 70 kg:

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 80 mg daily.

The maximum daily dose your doctor will prescribe for adults is 80mg.

Your doctor will tell you how long your treatment with **STRADENT** will last. Do not stop any treatment unless your doctor tells you to do so.

If you have the impression that the effect of **STRADENT** is too strong or too weak, tell your doctor or pharmacist.

If you take more STRADENT than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

The most commonly reported symptoms accompanying overdoses are gastrointestinal symptoms, sleepiness, dizziness, tremor, and abnormal behaviour.

If you forget to take STRADENT

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.



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If you stop taking STRADENT

If you stop taking Atomoxetine there are usually no side effects but your ADHD symptoms may return. You should talk to your doctor first before you stop treatment.

4. Possible side effects

STRADENT can have side effects.

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

If any of the following happens, stop taking **STRADENT** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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



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These are all very serious side effects. If you have them, you may have had a serious reaction to **STRADENT**. You may need urgent medical attention or hospitalisation.

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

Treatment with **STRADENT** in children can cause headache, stomach pain and decreased appetite. Stomach pain and decreased appetite normally resolve after a while.

Treatment with **STRADENT** in adults can cause decreased appetite, insomnia, headache, dry mouth and nausea.

Tell your doctor if you notice any of the following:

Frequent side effects:

| Children and adolescents over 6 years | Adults |
|--|--|
| Headache | Feeling sick (nausea) |
| Pain in the stomach | Dry mouth |
| Decreased appetite (not feeling hungry) | Headache |
| Feeling sick (nausea) | Decreased appetite (not feeling hungry) |
| Being sick (vomiting) | Problems getting to sleep, staying asleep and waking early |
| Sleepiness | |



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| Increased blood pressure | Increased blood pressure |
| Increased heart rate (pulse) | Increased heart rate (pulse) |
| Being irritable or agitated | Feeling agitated |
| Problems sleeping including waking early | Decreased interest in sex |
| Depression | Sleep disturbance |
| Large pupils (the dark centre of the eye) | Dizziness |
| Dizziness | An abnormal taste or change in taste that will not go away |
| Constipation | Tremor |
| Loss of appetite | Tingling or numbness in the hands or feet |
| Upset stomach, indigestion | Sleepiness, drowsy, feeling tired |
| Swollen, reddened and itchy skin | Constipation |
| Rash | Stomach ache |
| Tiredness | Indigestion |
| Weight loss | Wind (flatulence) |
| Mood swings | 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 |



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| | 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 |
|--|---|

Less frequent side effects:



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| 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 Abnormal skin sensation such as burning, prickling, itching or tingling | 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 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 |



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| | |
|--|-----------------|
| | Feeling anxious |
|--|-----------------|

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **STRADENT**.

5. How to store STRADENT

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep the container in the outer carton in order to protect from light.

Do not use after the expiry date stated on the packaging.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What STRADENT contains

The active substance is Atomoxetine hydrochloride

STRADENT 10 mg:

Each capsule contains 10 mg atomoxetine hydrochloride

STRADENT 18 mg:

Each capsule contains 18 mg atomoxetine hydrochloride





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STRADENT 25 mg:

Each capsule contains 25 mg atomoxetine hydrochloride

STRADENT 40 mg:

Each capsule contains 40 mg atomoxetine hydrochloride

STRADENT 60 mg:

Each capsule contains 60 mg atomoxetine hydrochloride

The other ingredients of **STRADENT** are Starch pregelatinised, simethicone emulsion.

Composition of the capsule:

10 mg - gelatin, titanium dioxide (CI no. 77891)

18 mg – gelatin, titanium dioxide (CI no. 77891), Iron oxide yellow (CI no. 77492)

25 mg – gelatin, titanium dioxide (CI no. 77891), FD&C Blue 2 (CI no. 73015)

40 mg - gelatin, titanium dioxide (CI no. 77891), FD&C Blue 2 (CI no. 73015)

60 mg - gelatin, titanium dioxide (CI no. 77891), Iron oxide yellow (CI no. 77492), FD&C Blue 2 (CI no. 73015)

Composition of the ink:

Black iron oxide (C.I. No. 77499), butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, strong ammonia solution

What STRADENT looks like and contents of the pack

STRADENT 10 mg

Off-white opaque / off-white opaque, size '5' hard gelatin capsules filled with white to off-white powder and imprinted with 'F' on off-white opaque cap and '41' on off-white opaque body with black ink

STRADENT 18 mg



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Golden opaque / off-white opaque, size '4' hard gelatin capsules filled with white to off-white powder and imprinted with 'F' on golden opaque cap and '42' on off-white opaque body with black ink

STRADENT 25 mg

Blue opaque / off-white opaque, size '4' hard gelatin capsules filled with white to off-white powder and imprinted with 'F' on blue opaque cap and '43' on off-white opaque body with black ink

STRADENT 40 mg

Blue opaque / blue opaque, size '2' hard gelatin capsules filled with white to off-white powder and imprinted with 'F' on blue opaque cap and '45' on blue opaque body with black ink.

STRADENT 60 mg

Blue opaque / golden opaque, size '1' hard gelatin capsules filled with white to off-white powder and imprinted with 'F' on blue opaque cap and '46' on golden opaque body with black ink

Presentation of STRADENT:

1. 30 capsules are packed in 25 micron PVC / 25 micron PE / 90 gsm PVdc Film - Aluminium foil blister pack. Each carton contains 3 blisters of 10 capsules each. The blisters are further packed in pre-printed cartons with leaflet
2. 30 capsules are packed in 25 micron OPA / 45 micron Al.foil / 60 micrometer PVC Film - Aluminium foil blister pack. Each carton contains 3 blisters of 10 capsules each. The blisters are further packed in pre-printed cartons with leaflet
3. 30 capsules are packed in white opaque round HDPE container closed with polypropylene stock ribbed closure with wad having induction sealing liner.



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Capsules shall be packed in HDPE container pack along with 1 g silica gel sachet.

The HDPE container will be further packed in pre-printed carton with package leaflet.

Not all packs and pack sizes are necessarily marketed.

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

AUROGEN SA (Pty) Ltd
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