1.5.5.4 PATIENT INFORMATION LEAFLET - CLEAN

SCHEDULING STATUS: S5

STRATEX 10 mg Capsules

STRATEX 18 mg Capsules

STRATEX 25 mg Capsules

STRATEX 40 mg Capsules

STRATEX 60 mg Capsules

STRATEX 80 mg Capsules

Atomoxetine hydrochloride
Sugar free

WARNING:

SUICIDAL IDEATION IN CHILDREN AND ADOLESCENTS

STRATEX (atomoxetine) increased the risk of suicidal ideation in children or adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD). Patients started on therapy should be closely monitored for suicidal thinking and behaviour, worsening of symptoms, or unusual changes in behaviour. Families and caregivers should be advised of the need for close observation and to discuss any concerns with your doctor.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- STRATEX has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What STRATEX is and what it is used for

STRATEX contains atomoxetine, which is used to increase attention and decrease impulsiveness and hyperactivity in patients with attention-deficit and hyperactivity disorder (ADHD).

STRATEX is used to treat ADHD in children over six years of age, adolescents and in 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 behavioral therapy.

It is not for use as a treatment for ADHD in children under 6 years of age.

Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist.

2. What you need to know before you take STRATEX

Do not take STRATEX if you:

- are hypersensitive (allergic) to atomoxetine or any of the other ingredients of STRATEX (listed in section 6);
- took a medicine known as a monoamine oxidase inhibitor (MAOI), for example phenelzine, in the last two weeks. A MAOI is sometimes used for depression and other mental-health problems; taking STRATEX 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 STRATEX before you take a MAOI;
- have or had liver problems;
- 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, as this may be an effect of STRATEX;
- have a tumour of your adrenal gland (phaeochromocytoma);
- have an eye disease called narrow-angle glaucoma (increased pressure in your eye).

Warnings and precautions

Both adults and children should be aware of the following warnings and precautions. Talk to your doctor or pharmacist before taking STRATEX if you have:

- thoughts about killing yourself or trying to kill yourself;
- problems with your heart (including heart defects) or an increased heartbeat: STRATEX can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects;
- cardiovascular disease (problems with your heart) or past medical history of stroke;
- sudden changes in your blood pressure and heart rate. STRATEX can increase your heart rate (pulse);
- high blood pressure: STRATEX can increase blood pressure;
- low blood pressure: STRATEX can cause dizziness or fainting in people with low blood pressure;
- liver problems. You may need a lower dose;
- different moods than usual (mood swings) or feel very unhappy;
- 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;

- possible allergic reactions, including severe allergic reactions known as anaphylaxis;
- a history of epilepsy or have had seizures for any other reason. STRATEX might lead to an increase in seizure frequency;
- if your child is not growing or gaining weight as expected;
- problems passing urine.
- have poor circulation which makes fingers and toes numb and pale (Raynaud's disease);
- 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 STRATEX can make these problems worse. Your doctor will want to monitor how STRATEX affects you.

STRATEX may cause the height and weight of children to lag behind the predicted norm for the first 9 to 12 months of treatment. Tell your doctor if this happens to your child and talk about your concerns. See POSSIBLE SIDE EFFECTS.

Important information about the content of the capsules

Do not open STRATEX capsules because 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.

Other medicines and STRATEX

Always tell your healthcare provider if you are taking any other medicine. This includes all complementary or traditional medicines.

Your doctor will decide if you can take STRATEX with your other medicines and in some cases your doctor may have to adjust your dose or increase your dose much more slowly.

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

If you are taking other medicines, STRATEX 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 STRATEX:

- Terbinafine (an antifungal medicine);
- Quinidine, amiodarone (medicines for heart rhythm disturbances);
- Various types of antidepressants, such as fluoxetine, paroxetine, imipramine, venlafaxine, mirtazapine, lithium, bupropion;
- Salbutamol (used for asthma);
- Antibiotics, such as moxifloxacin, erythromycin
- Neuroleptics (tranquilisers used to treat psychotic conditions) such as haloperidol, pimozide, chlorpromazine);
- Decongestants such as pseudoephedrine or phenylephrine, contained in various cough and cold medicines. These medicines may further increase your blood pressure;

- Thiazide diuretics (such as indapamide, hydrochlorothiazide;
- Mefloquine, chloroquine (medicines for malaria);
- Tramadol (used for severe pain);
- Tranquilisers such as diazepam (or other medicines in a group called benzodiazepines). Do not abruptly stop taking these without talking to your doctor, as sudden withdrawal may lead to seizures.

STRATEX with food and drink

You may take STRATEX without concern about mealtimes. Take STRATEX with water or a soft drink (see section 3: HOW TO TAKE STRATEX).

Pregnancy and breastfeeding

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 STRATEX.

It is not known if STRATEX may affect an unborn baby or pass into breast milk.

- STRATEX should not be used during pregnancy.
- You should either avoid taking STRATEX if you are breastfeeding or discontinue breastfeeding.

Driving and using machines

You may feel tired, sleepy or dizzy after taking STRATEX. You should be careful if you are driving a car or operating machinery until you know how

STRATEX affects you. If you feel tired, sleepy or dizzy you should not drive or operate machinery.

3. How to take STRATEX

Do not share medicines prescribed for you with any other person.

Always take STRATEX exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is taken one or two times a day (morning and late afternoon or early evening).

Children and adolescents over 70 kg body mass and adults:

STRATEX is usually started at a total daily dose of 40 mg for a minimum of 7 days. The maximum daily dose your doctor will prescribe is 80 mg.

If you have problems with your liver your doctor may prescribe a lower dose.

If you have the impression that STRATEX is too strong or too weak, you should talk to your doctor or pharmacist.

Your doctor will tell you how long your treatment with STRATEX will last.

If you are a child or adolescent (6 years or older):

Your doctor will tell you how much STRATEX 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 STRATEX you need to take according to your body weight.

The usual starting dose in approximately 0,5 mg/kg daily.

Do not give STRATEX to children under six years old.

Children should not take this medicine without the help from an adult.

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

The capsules should be swallowed whole, with water, and taken 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.

If you take more STRATEX than you should

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

Tell your doctor how many capsules you have taken. The most commonly reported symptoms accompanying overdoses are gastrointestinal symptoms, sleepiness, dizziness, tremor, and abnormal behaviour.

If you forget to take STRATEX

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 a forgotten dose.

If you stop taking STRATEX

If you stop taking STRATEX 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

STRATEX can have side effects.

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

If any of the following happens, stop taking / using STRATEX 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), itching
- feeling or having a very fast heartbeat, abnormal heartbeat, or severe pain on the chest
- stroke - you may feel a sudden numbness or weakness of the face, arm or leg (especially on one side of the body), confusion, trouble speaking or trouble seeing in one or both eyes
- signs of liver injury or jaundice:
  - 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.

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

Tell your doctor immediately or go to the casualty department of your nearest hospital if you notice any of the following:

- psychotic symptoms, including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious
- thinking about or feeling like killing yourself
- feeling aggressive
- feeling unfriendly and angry (hostility)
- mood swings or mood changes
- seizures (“fits”).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

Children and young people over 6 years:	*Adult patients*
• infections (influenza, sinus	• sinusitis

Children and young people over 6 years:	*Adult patients*
infections) • loss of appetite, anorexia (eating disorder) • being irritable or agitated • feeling anxious, depressed, feeling sad or hopeless • tics (an abrupt, uncontrollable movement or sound) • mood swings • headache • problems sleeping including waking early • dizziness • sedation • large pupils (the dark centre of the eye) • increased blood pressure • constipation, stomach discomfort • upset stomach, indigestion • nausea, vomiting • swollen, reddened and itchy skin	• decreased appetite • irritability, anxiety, mood swings, agitation • depression and depressed mood, sedation • sleepiness, sleep disorders, trouble sleeping • decreased libido • tics • headache • dizziness • an alteration in taste • an abnormal sensation, typically tingling or pricking (‘pins and needles’) • tremor (trembling) • increased heart rate, palpitations, quick heart beat • flushing, hot flushes • increased blood pressure • dry mouth • nausea, vomiting, dyspepsia, flatulence

Children and young people over 6 years:	*Adult patients*
• rash • feeling tired, feeling lazy (lethargy) • chest pain • weight loss	• constipation, stomach discomfort • sweating, rash, swollen, reddened and itchy skin • problems going to the toilet such as not be able to urinate, frequent or hesitant urinating, pain on urinating • menstrual cramps • inflammation of the prostate gland (prostatitis) • groin pain in men, failure to obtain an erection, retarded orgasm, difficulty maintaining an erection, decreased libido • lack of strength or energy, tiredness, feeling lazy (lethargy), chills, feeling irritable, feeling jittery • feeling thirsty • weight loss

Less frequent side effects

Children and young people over 6 years:	*Adult patients*
• fainting	• restlessness

Children and young people over 6 years:	*Adult patients*
• tremor • migraine • blurred vision • abnormal skin sensation, such as burning, prickling, itching, or tingling or numbness in the hands or feet • seizure (fits) • feeling or having a very fast heartbeat (QT prolongation) • shortness of breath • sweating too much • lack of strength or energy • poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease) • problems going to the toilet such as frequent or hesitant urinating, pain on urinating • prolonged and painful erections • groin pain in males • weakness	• fainting • migraine • reduced sense of touch or sensation • blurred vision • poor blood circulation which makes toes and fingers cold, or numb and pale (Raynaud's disease) • shortness of breath, runny nose • raised red itchy rashes (hives) • muscle spasms • an urge to urinate • abnormal or absence of orgasm • irregular menstruation • ejaculation failure • prolonged and painful erections • feeling cold

Effects on growth in children

Some children experience reduced growth (weight and height) when they start taking STRATEX. 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 STRATEX temporarily.

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. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of STRATEX.

5. How to store STRATEX

Store all medicines out of reach of children.

Store at or below 25 °C. Keep blisters in the originsl packaging until required for use.

Do not store in a bathroom.

Do not use this medicine after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What STRATEX contains

- The active substance is atomoxetine.

STRATEX 10 mg hard capsules

Each hard capsule contains atomoxetine hydrochloride equivalent to 10 mg atomoxetine.

- The other ingredients are:

Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.

Capsule shell: Gelatin, sodium lauryl sulfate (E487), titanium dioxide (E171)

STRATEX 18 mg hard capsules

Each hard capsule contains atomoxetine hydrochloride equivalent to 18 mg atomoxetine.

- The other ingredients are:

Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.

Capsule shell: Gelatin, sodium lauryl sulfate (E487), titanium dioxide (E171), iron oxide yellow (E172)

STRATEX 25 mg hard capsules

Each hard capsule contains atomoxetine hydrochloride equivalent to 25 mg atomoxetine.

- The other ingredients are:

Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.

Capsule shell: Gelatin, sodium lauryl sulfate (E487), titanium dioxide (E171), indigo carmine (E132)

STRATEX 40 mg hard capsules

Each hard capsule contains atomoxetine hydrochloride equivalent to 40 mg atomoxetine.

- The other ingredients are:

Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.

Capsule shell: Gelatin, sodium lauryl sulfate (E487), titanium dioxide (E171), indigo carmine (E132)

STRATEX 60 mg hard capsules

Each hard capsule contains atomoxetine hydrochloride equivalent to 60 mg atomoxetine.

- The other ingredients are

Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.

Capsule shell: Gelatin, sodium lauryl sulfate (E487), titanium dioxide (E171), indigo carmine (E132), iron oxide yellow (E172)

STRATEX 80 mg hard capsules

Each hard capsule contains atomoxetine hydrochloride equivalent to 80 mg atomoxetine.

- The other ingredients are

Capsule content: Pregelatinized maize starch, silica colloidal anhydrous and dimeticone.

Capsule shell: Gelatin, sodium lauryl sulfate (E487), titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172)

Printing ink (Black)

Contains: Shellac Glaze-45 % (20 % esterified) in ethanol, Iron oxide black (E172) and propylene glycol.

What STRATEX looks like and contents of the pack

STRATEX 10 is presented as a white powder in a hard gelatin capsule of size no 3, opaque white cap imprinted with ‘10’ and opaque white body imprinted with ‘mg’.

STRATEX 18 is presented as white powder in a hard gelatin capsule of size no. 3, opaque rich yellow cap imprinted with ‘18’ and opaque white body imprinted with ‘mg’.

STRATEX 25 is presented as white powder in a hard gelatin capsule of size no. 3, opaque blue cap imprinted with ‘25’ and opaque white body imprinted with ‘mg’.

STRATEX 40 is presented as white powder in a hard gelatin capsule of size no. 3, opaque blue cap imprinted with ‘40’ and opaque blue body imprinted with ‘mg’.

STRATEX 60 is presented as white powder in a hard gelatin capsule of size no. 2, opaque blue cap imprinted with ‘60’ and opaque rich yellow body imprinted with ‘mg’.

STRATEX 80 is presented as white powder in a hard gelatin capsule of size no. 2, opaque brown cap imprinted with ‘80’ and opaque white body imprinted with ‘mg’.

STRATEX capsules are packed in transparent PVC/PE/PCTFE-aluminium foil blisters or PA/AL/PVC-aluminium foil blisters. The strips are packed in a cardboard box containing 7, 14, 28 or 30 capsules.

Not all pack sizes are necessarily marketed at any one time.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets

Cape Town

8001

enquiries@unicornpharma.co.za

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