

<i>Applicant/PHCR:</i>	Macleods Pharmaceuticals SA (Pty) Ltd
<i>Name:</i>	Atomoxetine 10 mg, 18 mg, 25 mg, 40 mg, 60 mg and 80 mg capsules
<i>Active Ingredient:</i>	Atomoxetine hydrochloride
<i>Dosage Form:</i>	Capsules
<i>Date:</i>	21 August 2025

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JULY 2025

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APPROVED PATIENT INFORMATION LEAFLET JULY 2025

SCHEDULING STATUS:

S5

WARNING: SUICIDAL IDEATION IN CHILDREN AND ADOLESCENTS

ATOMAKTIN (atomoxetine) increased the chance of suicide thoughts in children or adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD). Anyone considering the use of ATOMAKTIN in a child or adolescent must balance this risk with the clinical need. Other diseases occurring with ADHD may be associated with an increase in the risk of suicidal thoughts and/or behaviour. Patients who are started on therapy should be watched closely for suicidality (suicidal thinking and behaviour), clinical worsening, or unusual changes in behaviour.

Families and caregivers should be advised of the need for close observation and communication with the prescriber. ATOMAKTIN is approved for ADHD in paediatric and adult patients. ATOMAKTIN is not approved for major depressive

ATOMAKTIN 10

Atomoxetine hydrochloride 10 mg

Sugar free

ATOMAKTIN 18

Atomoxetine hydrochloride 18 mg

Sugar free

ATOMAKTIN 25

Atomoxetine hydrochloride 25 mg

Sugar free

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ATOMAKTIN 40

Atomoxetine hydrochloride 40 mg

Sugar free

ATOMAKTIN 60

Atomoxetine hydrochloride 60 mg

Sugar free

ATOMAKTIN 80

Atomoxetine hydrochloride 80 mg

Sugar free

Read all of this leaflet carefully before you start taking ATOMAKTIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **ATOMAKTIN** 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 **ATOMAKTIN** is and what it is used for
2. What you need to know before you take **ATOMAKTIN**
3. How to take **ATOMAKTIN**
4. Possible side effects
5. How to store **ATOMAKTIN**
6. Contents of the pack and other information

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1. What ATOMAKTIN is and what it is used for

ATOMAKTIN contain atomoxetine.

ATOMAKTIN 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 or give ATOMAKTIN

Do not take or give ATOMAKTIN:

- If you are allergic to atomoxetine or any of the other ingredients of this medicine.
- 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 **ATOMAKTIN** with an MAOI could cause serious side effects or even be life-threatening
- If you have an eye disease called narrow-angle glaucoma (increased pressure in your eye)
- If you have a condition called pheochromocytoma (tumour of your adrenal gland)
- If you have uncontrolled high blood pressure
- If you have serious problems with your heart which may be affected by an increase in heart rate and or blood pressure.

Warnings and precautions

Talk to your doctor before taking **ATOMAKTIN** if you have

- thoughts about killing yourself or trying to kill yourself.
- problems with your heart (including heart defects) or an increased heartbeat. **ATOMAKTIN** can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects.

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- high blood pressure. **ATOMAKTIN** can increase blood pressure.
- low blood pressure. **ATOMAKTIN** 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. **ATOMAKTIN** 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.
- Possible allergic reactions including severe allergic reactions known as anaphylaxis
- Poor circulation which makes fingers and toes, numb and pale (Raynauds disease)
- If your child is not growing or gaining weight as expected.
- Problems passing urine.

Other medicines and ATOMAKTIN

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

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

Tell your doctor or pharmacist if you are taking any of the following medicines:

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- 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 get 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 **ATOMAKTIN** 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 **ATOMAKTIN**:

- 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)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **ATOMAKTIN**.

Do not take **ATOMAKTIN** if you are pregnant, are considering becoming pregnant or are breastfeeding.

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Driving and using machines

You may feel tired, sleepy or dizzy while taking **ATOMAKTIN**. If this happens, do not drive or use any tools or machines.

3. How to take ATOMAKTIN

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

Always take **ATOMAKTIN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Swallow your capsules whole with a drink of water.

- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition.
- If you are taking this medicine for a long time, your doctor will want to monitor you.

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

If you have the impression that the effect of **ATOMAKTIN** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ATOMAKTIN than you should

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

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If you forget to take ATOMAKTIN

It is important to take your **ATOMAKTIN** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking ATOMAKTIN

If **ATOMAKTIN** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **ATOMAKTIN** for as long as your doctor has prescribed.

4. Possible side effects

ATOMAKTIN can have side effects.

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

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

- Allergic reactions – the signs may include: sudden swelling of your face, lips or tongue, difficulty breathing, hives (small raised, itchy patches of skin)
- Dark urine (hepatitis)
- Yellow skin or eyes (jaundice)
- Stomach pain which is sore when you press it (tenderness) on the right side just below the

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ribs.(Abdominal pain)

- A feeling of sickness (nausea) that is unexplained.
- Tiredness(Fatigue)
- Itching (Dermatitis)

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

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

- feeling or having a very fast heartbeat, abnormal rhythms of the heart
- thinking about or feeling like killing yourself (Suicide-related events)
- feeling aggressive (agitation)
- feeling unfriendly and angry (hostility)
- mood swings or mood changes

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

Tell your doctor if you notice any of the following side effects:

Frequent

- Headache
- Pain in the stomach (Abdominal pain)
- Decreased appetite (not feeling hungry)
- feeling sick (nausea)
- Being sick (vomiting)
- Sleepiness (somnolence)

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- 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 (Anorexia)
- Upset stomach, indigestion
- Swollen, reddened and itchy skin (Dermatitis)
- Rash
- Tiredness
- Weight loss
- Mood swings
- Fainting (somnolence)
- Lack of strength or energy (Lethargy)
- Decreased sex drive
- Tremor
- Dry mouth
- Headache
- Hot flushes
- *Less frequent*
- Blurred vision
- Problems going to the toilet such as frequent or hesitant urination
- Abnormal skin sensation, such as burning, prickling, itching or tingling

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- Menstrual cramps
- Painful, prolonged erection
- Ejaculation failure

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

Should your general health worsen or if you experience any untoward effects while taking **ATOMAKTIN**, please consult your healthcare provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or report to safety@macleodspharma.com. By reporting side effects, you can help provide more information on the safety of **ATOMAKTIN**.

5. How to store ATOMAKTIN

Store at or below 25 °C.

KEEP OUT OF THE REACH OF CHILDREN.

Keep the blisters in the carton until required for use.

6. Contents of pack and other information

What ATOMAKTIN contains

The active ingredient is atomoxetine.

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Sugar free

The other ingredients are:

Pregelatinized starch,

Colloidal silicon dioxide

ATOMAKTIN 10 contains gelatin, SLS, titanium dioxide

ATOMAKTIN 18 contains gelatin, SLS, iron oxide yellow, titanium dioxide

ATOMAKTIN 25 contains gelatin, SLS, iron oxide yellow, titanium dioxide

ATOMAKTIN 40 contains gelatin, SLS, iron oxide yellow, titanium dioxide

ATOMAKTIN 60 contains gelatin, SLS, iron oxide yellow, Indigo carmine, titanium dioxide

ATOMAKTIN 80 contains gelatin, SLS, iron oxide yellow, Indigo carmine, titanium dioxide

What ATOMAKTIN looks like and contents of the pack

ATOMAKTIN 10: Opaque white cap/ opaque white body size “3” capsules containing white to off white powder, with ‘I 23’ on body imprinted with black ink.

ATOMAKTIN 18: Gold cap/ opaque white body size “3” capsules containing white to off white powder, with ‘I 24’ on body imprinted with black ink.

ATOMAKTIN 25: Opaque blue cap/ opaque white body size “3” capsules containing white to off white powder, with ‘I 25’ on body imprinted with black ink.

ATOMAKTIN 40: Opaque blue cap/ opaque blue body size “3” capsules containing white to off white powder, with ‘I 26’ on body imprinted with black ink.

ATOMAKTIN 60: Opaque blue cap/ gold body size “2” capsules containing white to off white powder, with ‘I 27’ on body imprinted with black ink.

ATOMAKTIN 80: Opaque brown cap/ opaque white body size “2” capsules containing white to off white powder, with ‘I 28’ on body imprinted with black ink.

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Contents of the pack:

Clear PVC/PVdC – Al blister pack: Blister pack consist of Clear PVC/PVdC (250µ/90 GSM) as the forming material and plain 25µ Aluminium foil with 6-8 GSM heat seal lacquer coating as the lidding material.

Pack sizes include 14s, 28s & 30s capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

MACLEODS PHARMACEUTICALS SA (PTY) LTD

Ground Floor, Block 1,

Bassonia Estate Office Park (East),

1 Cussonia Drive,

Bassonia Rock Ext 12

Alberton

Gauteng

This leaflet was last revised in

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Registration numbers

ATOMAKTIN 10: 56/1.2/1141

ATOMAKTIN 18: 56/1.2/1142

ATOMAKTIN 25: 56/1.2/1143

ATOMAKTIN 40: 56/1.2/1144

ATOMAKTIN 60: 56/1.2/1145

ATOMAKTIN 80: 56/1.2/1146

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Access to the corresponding Professional Information

The corresponding professional information can be accessed at <https://www.macleodspharma.com>
or email macleodsrso@macleodspharma.com or contact 011 682 1169

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