| | |
|---|---|
| **Applicant: Teva Pharmaceuticals (Pty) Ltd** | **Product name: ATTENTRA 10, 18, 25, 40, 60 & 80**<br>**Dosage form & strength:** Capsules<br><br>Atomoxetine hydrochloride equivalent to 10 mg, 18 mg, 25 mg, 40 mg, 60 mg & 80 mg atomoxetine. |
| **Date of Registration: 11.08.2020** | **SAHPRA approval date: 9.07.2025** |

## PATIENT INFORMATION LEAFLET

**PATIENT INFORMATION LEAFLET:**

**SCHEDULING STATUS:**

**S5**

**ATTENTRA 10, 18, 25, 40, 60, 80 mg capsules**

**Atomoxetine hydrochloride**

**Sugar free.**

**WARNING: SUICIDAL IDEATION IN CHILDREN AND ADOLESCENTS**

**ATTENTRA increases the risk of suicidal ideation in children or adolescents with Attention-Deficit Hyperactivity Disorder (ADHD). Anyone considering the use of ATTENTRA in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be monitored closely 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 communication with the prescriber. ATTENTRA is approved for ADHD in paediatric and adult patients. ATTENTRA is not approved for major depressive disorder.**

**Read all of this leaflet carefully before you start taking ATTENTRA.**

- 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.
- ATTENTRA 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 ATTENTRA IS AND WHAT IT IS USED FOR:

ATTENTRA contains the active ingredient atomoxetine (as atomoxetine hydrochloride).

ATTENTRA is used to treat attention-deficit and hyperactivity disorder (ADHD):

- in children over six years of age
- in young people
- in adults.

**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 ATTENTRA:

**Do not take ATTENTRA if you:**

- Are hypersensitive (allergic) to atomoxetine (as atomoxetine hydrochloride), or to any of the other ingredients of ATTENTRA.
- Are taking 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 ATTENTRA with a MAOI could cause serious side effects or be life-threatening. You also need to wait at least 14 days after you stop taking ATTENTRA before you take a MAOI.
- Have an eye disease called narrow-angle glaucoma (increased pressure in your eye).
- 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 ATTENTRA.
- Have serious problems with the blood vessels in your brain - such as a stroke, swelling and

weakening of part of a blood vessel (aneurysm) or narrow or blocked blood vessels.

- Have a tumour of your adrenal gland (pheochromocytoma).
- Have impaired liver function.

**Warnings and precautions:**

Take special care with ATTENTRA if you:

- Develop thoughts about killing yourself or try to kill yourself.
- Have problems with your heart (including heart defects) or an increased heartbeat. ATTENTRA can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects.
- Have high blood pressure. ATTENTRA can increase blood pressure.
- Have low blood pressure. ATTENTRA can cause dizziness or fainting in people with low blood pressure.
- Have problems with sudden changes in your blood pressure or your heart rate.
- Have cardiovascular disease or past medical history of stroke.
- Have liver problems. You may need a lower dose.
- Have psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious.
- Have mania (feeling elated or over-excited, which causes unusual behaviour) and agitation.
- Have aggressive feelings.
- Have unfriendly and angry (hostile) feelings.
- Have a history of epilepsy or have had seizures for any other reason. ATTENTRA might lead to an increase in seizure frequency.
- Have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words.
- Have Raynaud’s phenomenon which is a discolouration of the fingers and/or the toes after exposure to changes in temperature (cold or hot) or emotional events.
- Have problems with your bladder such as difficulty passing urine while taking ATTENTRA, you should inform your doctor.

If you are a child or teenager your doctor will monitor your height and weight during your treatment with ATTENTRA. Please inform your doctor if you notice any weight loss or slowed growth while taking ATTENTRA.

**Serotonin syndrome:**

Serotonin syndrome is a potentially life-threatening condition which may occur when taking ATTENTRA in combination with some other medicines (see **section 2 - Other medicines and ATTENTRA**). Signs and symptoms of serotonin syndrome may include a combination of the following: confusion, restlessness, incoordination and rigidity, hallucinations, coma, fast heartbeat, increased body temperature, fast changes in blood pressure, sweating, flushing, tremor, overactive reflexes, nausea, vomiting, and diarrhoea. Contact a doctor or go to your nearest emergency department immediately if you think serotonin syndrome is happening to you.

Treatment with ATTENTRA may make you feel aggressive, hostile or violent; or aggravate these symptoms if they were present before treatment. It may also cause you to have unusual changes in behaviour or mood (including physical assault, threatening behaviour and thoughts of harming others). If you or your family and/or friends notice any of these reactions, talk to your doctor or pharmacist right away.

**Other medicines and ATTENTRA:**

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

ATTENTRA may affect or be affected by other medicines. These include:

- Some anti-depressants, opioids as tramadol, and medicines used to treat migraine called triptans. These medicines may interact with ATTENTRA and can lead to serotonin syndrome, a potentially life-threatening condition. (See **section 2, Warnings and precautions, Serotonin syndrome**).

Do not take ATTENTRA with medicines called MAOIs (monoamine oxidase inhibitors) used for

depression.

If you are taking any of the following medicines, check with your doctor or pharmacist before taking ATTENTRA:

- medicines that increase blood pressure or are used to control blood pressure
- medicines such as antidepressants, for example imipramine, venlafaxine, mirtazapine, fluoxetine and paroxetine
- salbutamol (a medicine used 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
- medicines used to suppress abnormal rhythms of the heart
- antibiotics called moxifloxacin or erythromycin
- medicines called methadone, mefloquine, lithium or cisapride
- high blood pressure medicine, including medicines belonging to the thiazide diuretic group, e.g. indapamide, hydrochlorothiazide
- some medicines used to treat mental health conditions
- medicines that are known to increase the risk of seizures (phenothiazines or butyrophenone, mefloquine, chloroquine, bupropion or tramadol)
- medicines called benzodiazepines due to the potential of withdrawal seizures.

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

**ATTENTRA with food and drink:**

ATTENTRA can be taken with or without food.

**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 ATTENTRA.

You should not take ATTENTRA if you are pregnant or while breastfeeding your baby.

**Driving and using machines:**

It is not always possible to predict to what extent ATTENTRA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in driving a vehicle or use machines until they are aware of the measure to which ATTENTRA affects them.

ATTENTRA has a minor influence on the ability to drive and use machines. ATTENTRA has been associated with increased rates of fatigue, somnolence and dizziness. Patients should be advised to use caution when driving a car or operating hazardous machinery until they are reasonably certain that their performance is not affected by ATTENTRA.

**3. HOW TO TAKE ATTENTRA:**

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

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

The capsules should be swallowed whole, 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 are a child or teenager (6 years or older):**

Your doctor will tell you how much ATTENTRA you should take and will calculate this according to your weight. He/she will normally start you on a lower dose before increasing the amount of ATTENTRA 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.

***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.

ATTENTRA should not be used in children under 6 years of age.

**Adults:**

ATTENTRA should be started at a 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 is 80 mg.

If you have problems with your liver or end-stage renal disease your doctor may prescribe a lower dose.

Taking ATTENTRA at the same time each day will have the best effect. It will also help you remember when to take it.

Your doctor will tell you how long your treatment with ATTENTRA will last. Do not stop treatment early. If you have the impression that the effect of ATTENTRA is too strong or too weak, tell your doctor or pharmacist.

**If you take more ATTENTRA than you should:**

In the event of overdosage, 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. Very rarely, serotonin syndrome has also been reported, a potentially life-threatening condition. (See **section 2, Warnings and precautions, Serotonin syndrome**).

**If you forget to take ATTENTRA:**

Do not take a double dose to make up for forgotten individual doses. If you miss a dose, you should take it as soon as possible; however, you should not take more than the prescribed total daily amount of ATTENTRA in any 24-hour period.

**4. POSSIBLE SIDE EFFECTS:**

ATTENTRA can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting (dizziness).

These are all very serious side effects. If you have them, you may have had a serious reaction to ATTENTRA. 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:

***Less frequent occurrence:***

- 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)
- seizures
- psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious.

Children and young adults have an increased risk of side effects:

- thinking about or feeling like killing yourself

- mood swings or mood changes.

Tell your doctor if you notice any of the following:

***Frequent occurrence:***

*Children, young adults and adults:*

- decreased appetite and loss of appetite
- difficulty falling asleep and/or staying asleep, irritability, anxiety, depression and depressed mood, tics (habitual spasmodic contraction of the muscles)
- headache, general feeling of unwellness, dizziness
- dilation of the pupil of the eye
- abdominal pain, vomiting, nausea, constipation, indigestion
- skin reactions - red, swollen and sore, sometimes with small blisters, rash
- fatigue, a lack of energy and enthusiasm
- blood pressure increase, heart rate increase, weight decrease.

*Adults only:*

- decreased sexual desire
- distortion of the sense of taste; abnormal sensation (typically tingling or pricking); trembling
- feelings or sensations that your heart is pounding or racing
- flushing, hot flush
- dry mouth, constipation, farting
- painful or difficult urination; extraordinary daytime urinary frequency; trouble starting or maintaining a urine stream; inability to completely or partially empty the bladder
- painful menstruation, typically involving abdominal cramps
- disorder of the discharge of semen from the male reproductive tract; inability to get or keep an erection firm enough to have sexual intercourse; swelling and inflammation of the prostate gland; male genital pain
- abnormal physical weakness or lack of energy
- chills, feeling jittery, thirst.

***Less frequent occurrence:***

*Children, young adults and adults:*

- temporary loss of consciousness, tremor, migraine, reduced sense of touch or sensation, seizures
- blurred vision, infection of the eye causing redness
- Raynaud's phenomenon (medical condition in which spasm of arteries cause episodes of reduced blood flow)
- difficult or laboured breathing
- abnormal liver function tests, jaundice (a condition in which the skin, whites of the eyes and mucous membranes turn yellow), inflammatory condition of the liver, liver injury, acute liver failure
- excessive sweating
- prolonged erection of the penis.

*Adults only:*

- a sudden, compelling urge to urinate
- ejaculation failure, menstruation irregular, orgasm abnormal
- feeling cold, chest pain.

***The following may also occur;***

*Children and young people over 6 years:*

- involuntary teeth grinding (bruxism).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

**5. HOW TO STORE ATTENTRA:**

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Store in the original container until required for use.

Do not use after the expiry date stated on the label/carton/bottle.

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 ATTENTRA contains:**

The active substance is atomoxetine (as atomoxetine hydrochloride).

***Capsule content:***

Co-processed maize starch consisting of maize starch and pregelatinised starch

Dimethicone 350 cs

Sodium starch glycolate (type A)

***Capsule shell:***

Gelatin

Titanium dioxide

For 18 mg: yellow iron oxide (E172)

For 25 mg and 40 mg: indigotine (E132) and black iron oxide (E172)

For 60 mg: indigotine (E132), black iron oxide (E172) and yellow iron oxide (E172)

For 80 mg: yellow iron oxide (E172) and red iron oxide (E172)

***Printing ink:***

Shellac

Propylene glycol

Ammonia solution

Black iron oxide (E172)

Potassium hydroxide

**What ATTENTRA looks like and contents of the pack:**

ATTENTRA 10: size 4 capsules, white opaque cap and body imprinted with ‘A910’ on both cap and body in black ink.

ATTENTRA 18: size 3 capsules, gold opaque cap and white opaque body imprinted with ‘A918’ on both cap and body in black ink.

ATTENTRA 25: size 3 capsules, blue opaque cap and white opaque body imprinted with ‘A925’ on both cap and body in black ink.

ATTENTRA 40: size 2 capsules, blue opaque cap and body imprinted with ‘A940’ on both cap and body in black ink.

ATTENTRA 60: size 2 capsules, blue opaque cap and gold opaque body imprinted with ‘A960’ on both cap and body in black ink.

ATTENTRA 80: size 1 capsules, brown opaque cap and white opaque body imprinted with ‘A980’ on both cap and body in black ink.

Opaque PVC/PVdC/PVC & aluminium blister strips in an outer cardboard carton.

White HDPE container with white polypropylene closure.

Pack sizes: 7, 14, 28, 30, 56, 60, 100, 250 capsules.

Not all pack sizes may be marketed.

**Holder of Certificate of Registration:**

Teva Pharmaceuticals (Pty) Ltd,

Maxwell Office Park,

Magwa Crescent West,

Waterfall City, Midrand,

Gauteng, South Africa,

2090

Tel: (011) 055 0200

**This leaflet was last revised in:**

9 July 2025

**Registration numbers:**

ATTENTRA 10: 50/1.2/0591

ATTENTRA 18: 50/1.2/0592

ATTENTRA 25: 50/1.2/0593

ATTENTRA 40: 50/1.2/0594

ATTENTRA 60: 50/1.2/0595

ATTENTRA 80: 50/1.2/0596

**Access to the corresponding Professional Information:**

***Website:*** https://www.teva.co.za/

***The Professional Information can also be obtained from:***

Teva Pharmaceuticals (Pty) Ltd,

Maxwell Office Park,

Magwa Crescent West,

Waterfall City, Midrand,

Gauteng, South Africa,

2090

Tel: (011) 055 0200