PATIENT INFORMATION LEAFLET

ATTENCIT RANGE

SCHEDULING STATUS:

S5

ATTENCIT 10 mg, hard gelatine capsule

ATTENCIT 18 mg, hard gelatine capsule

ATTENCIT 25 mg, hard gelatine capsule

ATTENCIT 40 mg, hard gelatine capsule

ATTENCIT 60 mg, hard gelatine capsule

ATTENCIT 80 mg, hard gelatine capsule

ATTENCIT capsules are sugar free.

Read all of this leaflet carefully before you start taking ATTENCIT

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

1. What ATTENCIT is and what it is used for

ATTENCIT contains atomoxetine, one of a group of medicines called psychoanaleptics. ATTENCIT increases the amount of norepinephrine (noradrenalin) in the brain.

This is a chemical that is produced naturally and increases attention and decreases impulsiveness and hyperactivity.

ATTENCIT 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 ATTENCIT

Do not take ATTENCIT:

- if you are hypersensitive (allergic) to atomoxetine or any of the other ingredients of ATTENCIT listed in section 6
- if you have uncontrolled high blood pressure, heart failure, serious heart problems, chest pain, problems with blood vessels in the brain (such as blood vessels weakening or stroke)
- if you have a liver function problem
- if you have or have had a tumour on the adrenal gland called pheochromocytoma
- if you have jaundice (yellowing of the skin and eyes) or high levels of liver enzymes
- if you have an eye disease called narrow-angle glaucoma (increased pressure in your eye)
- if you are taking a monoamine oxidase inhibitor (MAOI), for example anti-depression medicines such as phenelzine, or an antibiotic called linezolid; or if you stop taking a MAOI less than two weeks before starting treatment with ATTENCIT.

Warnings and precautions

Children and adolescents are more prone to have suicidal thoughts or feeling hostile, aggressive, and angry or have uncontrollable episodes of crying and/or laughing.
Children should be closely monitored for any of these behaviours once they start treatment with ATTENCIT.
The risks of these behaviours are higher if your child has a personal or family history of mood disorders.
Inform your doctor or healthcare provider immediately if you notice any suicidal or related behaviour.

Take special care with ATTENCIT

Tell your doctor:

- if you have problems with your heart (including heart defects) or an increased heartbeat. ATTENCIT can increase your heart rate (pulse). Sudden death has been reported in patients with heart defects
- if you have possible allergic reactions including severe allergic reactions, rash, or swelling
- if you have high blood pressure as ATTENCIT can increase blood pressure
- if you have low blood pressure as ATTENCIT can cause dizziness or fainting in people with low blood pressure
- if you have cardiovascular disease or past medical history of stroke
- if you experience a rapid, strong or irregular heartbeat, chest pain during active moments, unexplained fall of blood pressure, shortness of breath or other chest problems, you should get a check-up at the heart specialist
- if you experience a raised heart rate and/or blood pressure, heart problems, problems with blood circulation in the brain (previously had a stroke), prone to getting dizzy when standing up after sitting or lying down

- if you have poor circulation which makes fingers and toes numb and pale (Raynaud's phenomenon)
- if you have itchy skin, dark urine, yellowing skin (jaundice), tenderness of the upper right abdomen or unexplained flu-like symptoms, it could be possible that you have liver problems
- if you experience hallucinations (hearing voices or seeing things that are not there), delusional thinking (believing things that are not true, or being suspicious), over activity, euphoria, over excitement, agitation, hostility, aggression
- if you have aggressive, unfriendly, angry or suicidal feelings, exaggerated changes in mood such as uncontrollable laughing or crying, irritable or bad temper
- if you have a history of epilepsy, suffer from seizures or have a history of suffering from seizures as ATTENCIT may increase the frequency of seizures (see Other medicines with ATTENCIT)
- if you suffer from depression and being treated with ATTENCIT, as this medicine is not to treat depression
- if you experience anxiety, depressed mood or hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words
- if your child is not growing or gaining weight as expected while taking ATTENCIT
- if your child is under 6 years of age, as safety and efficacy have not been established in this age group
- if you are elderly
- if you have problems passing urine.

If you open the capsules, as the contents may irritate your eyes. If the capsule content comes into contact with your eyes, flush your eyes with water immediately and go to your nearest doctor or hospital.

Other medicines and ATTENCIT

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

- Monoamine oxidase receptor agonists (MAOIs), used to treat depression, or an antibiotic called linezolid should not be used together with ATTENCIT
- Medicines to treat major depression, panic disorder, anxiety (such as fluoxetine, paroxetine, imipramine, venlafaxine, mirtazapine), quinidine (to treat abnormal heartbeat and/or malaria), terbinafine (to treat fungal skin infections) may require a dose adjustment of ATTENCIT
- Beta-adrenergic receptor agonists such as salbutamol (a medicine swallowed as a tablet or syrup, inhaled or injected to treat asthma) when taken by mouth or injected may make you feel as if your heart is racing or increase your blood pressure. Your doctor will monitor your heart rate and blood pressure and may adjust the dosage of either medicine
- Medicines that affect heart rhythms (such as certain antipsychotics, class IA and III anti-dysrhythmics, moxifloxacin, erythromycin, methadone, mefloquine, tricyclic antidepressants, lithium, or cisapride), medicines that cause electrolyte imbalance (such as thiazide diuretics), and medicines that inhibit a liver enzyme called CYP2D6 may increase the risk of abnormal heart rhythm when taken with ATTENCIT
- Medicines known to increase risk of seizures e.g. antidepressants (tricyclic antidepressants, Selective Serotonin Reuptake Inhibitors (SSRIs), or buproprion), medicines used to treat mental disorders (neuroleptics or phenothiazines, butyrophenone), medicines used to treat malaria (mefloquine, chloroquine), or tramadol (pain medicine). In addition, caution is advised when stopping treatment with benzodiazepines (treatment for anxiety, insomnia, muscle spasms and alcohol withdrawal) while taking ATTENCIT, as there is a risk of potential withdrawal seizures
- Medicines that are used to control blood pressure, as taking them in combination with ATTENCIT may reduce their effectiveness
- The effects of midazolam, used to treat anxiety, may be stronger if taken with ATTENCIT
- Some cough and cold remedies which contain medicines that can affect blood pressure such as pseudoephedrine or phenylephrine. It is important to check with your pharmacist when buying any of these products.

ATTENCIT with food and drink

ATTENCIT can be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before using ATTENCIT.

You should not take ATTENCIT is you are pregnant or breastfeeding.

Driving and using machines

ATTENCIT may make your feel tired, sleepy or dizzy.

It is not always possible to predict to what extent ATTENCIT 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 ATTENCIT affects them.

3. How to take ATTENCIT

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

Always take ATTENCIT exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

ATTENCIT can be taken with or without food.

Do not open ATTENCIT capsule as it can cause irritation to your eyes (see Take special care with ATTENCIT).

If the contents of the capsules come into contact with your eyes, immediately flush the affected eye with water and seek medical advice from your healthcare provider.

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.

Your child or teenager (6 years or older):

Your doctor will tell you how much ATTENCIT you should take and will calculate this according to your weight. You will normally start treatment on a lower dose before your doctor increases the amount of ATTENCIT you need to take.

- **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 a maintenance dose of approximately 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. The maximum daily dose your doctor will prescribe is 80 mg.

Adults over 70 kg body weight:

- The usual starting total daily dose is 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 kidney, your doctor may prescribe a lower dose.

Your doctor will tell you how long your treatment with ATTENCIT will last. Do not stop treatment early because your condition may not have been treated adequately, and your symptoms may return.
If you have the impression that the effect of ATTENCIT is too strong or too weak, tell your doctor or pharmacist.

If you take more ATTENCIT than you should:

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

Symptoms of overdose may include:

- drowsiness, dizziness, seizures, shaking, increased uncontrolled movements
- feeling agitated, hyperactivity, abnormal behaviour
- gastrointestinal symptoms
- dilated pupils, increased heart rate or blood pressure, dry mouth.

If you forget to take ATTENCIT

If you forget to take ATTENCIT, take a dose as soon as you remember, but do not exceed the total daily amount prescribed to you in any 24 hours period, then continue to take ATTENCIT at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ATTENCIT

If you stop taking ATTENCIT 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

ATTENCIT can have side effects.

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

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

Adults, children (6 years and older) and teenagers:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing

- rash or itching
- fainting.

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

For children (6 years and older) and teenagers:

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

- thinking about or feeling like killing yourself
- seizures
- yellowing of the skin and eyes caused by liver or blood problems (jaundice)
- changes in the way your heart beats, for example, if you notice it is beating faster, high or low blood pressure, experience a heart attack or stroke
- difficulty breathing
- less urine than is normal for you, difficulty urinating
- liver infection (hepatitis), abdomen pain which is sore when you press it (tenderness) on the right side just below your ribs.

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:

- aggressiveness, hostility, irritation, mood swings, problems sleeping, agitation, anxiousness, depression, depressed mood, general feeling of unease
- headache, dizziness, sleepiness, drowsiness, tingling or prickling sensation (pins and needles)
- dilation of the pupil of the eye
- belly pain, stomach discomfort, constipation, indigestion, nausea, vomiting

- decreased appetite, decreased weight, loss of appetite
- tiredness, lack of energy, chest pain
- skin rash, severe itching of the skin, red, swollen, and sore skin
- increased blood pressure, low blood pressure when moving from a laying or sitting position.

Less frequent side effects:

- anger, uncontrollable laughter and/or tears, thoughts and/acts, hallucinations (seeing or hearing things that are not there)
- migraine, reduced sense of touch or sensation (numbness), tremors, tics
- blurred vision, conjunctivitis (pink-eye)
- abnormal/increased liver function test results
- excessive sweating
- male genital pain, painful erection
- physical weakness, lack of energy
- sinusitis, runny nose, cough.

The following side effects have been reported but the frequency for them to occur is not known:

- picking at your skin uncontrollably, mania (periods of great excitement or euphoria, delusions, and overactivity), elation, hyperactivity, delusional thinking
- poor blood circulation which makes toes and fingers numb and pale (Raynaud's disease).

For adults:

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

- thinking about or feeling like killing yourself
- seizures

- yellowing of the skin and eyes caused by liver or blood problems (jaundice)
- chest pain, changes in the way your heart beats, for example, if you notice it is beating faster, palpitations, irregular heartbeat, high blood pressure, experiencing a heart attack or stroke
- difficulty breathing
- less urine than is normal for you, difficulty urinating
- liver infection (hepatitis), abdomen pain which is sore when you press it (tenderness) on the right side just below your ribs, liver failure.

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:

- decreased appetite, decreased weight
- sleep disorder, agitation, decreased sex drive, problems sleeping, early morning awakening
- headache, dizziness, sleepiness, drowsiness, tingling or prickling sensation (pins and needles), tremors, lingering unpleasant taste in the mouth
- hot flushes, flushing
- abdominal discomfort, belly pain, stomach discomfort, nausea, vomiting, constipation, indigestion, flatulence (excessive wind), dry mouth
- skin rash, red, swollen, and sore skin, sometimes with small blisters, excessive sweating
- need to urinate more often than normal, painful, burning sensation or difficult urination
- erection problem, ejaculation disorder, menstrual cramps and pain, prostate infection, male genital pain (between the navel and groin)
- tiredness, chills, lack of energy, feeling jittery, irritability, thirst.

Less frequent side effects:

- restlessness

- migraine, reduced sense of touch or sensation (numbness), tics
- blurred vision
- cold hands and feet
- abnormal or increased liver function test results
- severe itching of the skin, skin rash round, red welts that itch
- muscle spasms
- sudden urge to urinate
- ejaculation problem or failure, abnormal orgasm, painful or prolonged erection, menstruation disorder, irregular menstruation
- feeling cold, abnormal physical weakness or lack of energy.

The following side effects have been reported but the frequency for them to occur is not known:

- anxiety, depression, depressed mood, aggression, hostility, anger, uncontrollable laughter and/or tears, mood swings, uncontrollable thoughts and/or acts, hallucinations, overactive imagination, hyperactivity, elation (mania), sensory disturbances, delusional thinking (bizarre thoughts)
- poor blood circulation which makes the fingers and toes numb and pale (Raynaud's disease), blood circulation disorder that causes the blood vessels outside of your heart and brain to narrow, block, or spasm
- sinusitis, runny nose, cough.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reporting Form**", found online under SAHPRA's publications: https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf. By reporting side effects, you can help

provide more information on the safety of ATTENCIT.

5. How to store ATTENCIT

Store all medicines out of reach of children.

Store at or below 30 °C in original blister packs or HDPE containers.

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

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 ATTENCIT contains

The active substance is atomoxetine.

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

The other ingredients are corn starch, dimethicone, hard gelatine capsule, pregelatinised starch, sodium starch glycolate.

Composition of hard gelatine capsules:

Gelatine, titanium dioxide (E171), yellow iron oxide (E172), indigotine – FD&C Blue 2 (E132), black iron oxide (E172), red iron oxide (E172), black printing ink.

What ATTENCIT looks like and contents of the pack

10 mg, capsule size 4, white opaque cap and body imprinted with A910 on cap and body in black ink.

18 mg, capsule size 3, gold opaque cap and white opaque body imprinted with A918 on cap and body in black ink.

25 mg, capsule size 3, blue opaque cap and white opaque body imprinted with A925 on both cap and body in black ink.

40 mg, capsule size 2, blue opaque cap and body imprinted with A940 on both cap and body in black ink.

60 mg, capsule size 2, blue opaque cap and gold opaque body imprinted with A960 on both cap and body in black ink.

80 mg, capsule size 1, brown opaque cap and white opaque body imprinted with A980 on both cap and body in black ink.

ATTENCIT capsules are packed in opaque PVC/PVdC/PVC/aluminium blister packs of 10 or 14 then placed in an outer carton. Each carton contains 28 or 30 capsules.

ATTENCIT capsules are packaged in high density polyethylene (HDPE) containers with polypropylene closures. Bottles contain either 28, 30, 100 or 250 capsules.

Holder of Certificate of Registration

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ATTENCIT 80 mg: A51/1.2/0381