PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

ARIPIPRAZOLE 5 KIARA tablets

ARIPIPRAZOLE 10 KIARA tablets

ARIPIPRAZOLE 15 KIARA tablets

ARIPIPRAZOLE 30 KIARA tablets

Aripiprazole

Contains sugar

Each ARIPIPRAZOLE 5 KIARA tablet contains 68,2 mg lactose monohydrate.

Each ARIPIPRAZOLE 10 KIARA tablet contains 63,2 mg lactose monohydrate.

Each ARIPIPRAZOLE 15 KIARA tablet contains 94,8 mg lactose monohydrate.

Each ARIPIPRAZOLE 30 KIARA tablet contains 189,6 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking ARIPIPRAZOLE KIARA

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

What is in this leaflet

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

3. How to take ARIPIPRAZOLE KIARA
4. Possible side effects
5. How to store ARIPIPRAZOLE KIARA
6. Contents of the pack and other information

1. What ARIPIPRAZOLE KIARA is and what it is used for

ARIPIPRAZOLE KIARA contains the active ingredient aripiprazole which belongs to a group of medicines called antipsychotic medicines.

ARIPIPRAZOLE KIARA is used to treat adults who suffer from a disease characterised by symptoms, such as hearing, seeing or sensing things which are not there, suspiciousness, mistaken beliefs, incoherent speech and behaviour and emotional flatness. People with this condition may also feel depressed, guilty, anxious or tense.

ARIPIPRAZOLE KIARA is used to treat adults who suffer from a condition with symptoms such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. It also prevents this condition from returning in patients who have responded to the treatment with ARIPIPRAZOLE KIARA.

2. What you need to know before you take ARIPIPRAZOLE KIARA

Do not take ARIPIPRAZOLE KIARA

- If you are hypersensitive (allergic) to aripiprazole or to any of the ingredients of ARIPIPRAZOLE KIARA listed in section 6 of this leaflet.
- If you are under the age of 18 years.

Warnings and precautions

Suicidal thoughts and behaviours have been reported during ARIPIPRAZOLE KIARA treatment. Tell your doctor immediately if you are having any thoughts or feelings about hurting yourself.

Before you start taking ARIPIPRAZOLE KIARA, tell your doctor if you suffer from:

- Cardiovascular problems or disease (diseases of the heart and circulation) or have a family history of heart problems or stroke.
- High blood pressure, a low blood volume or are dehydrated.
- Blood clots or have a family history of blood clots.
- Fits (seizures), since your doctor may want to monitor you more closely.
- High blood sugar, diabetes mellitus (characterised by symptoms such as excessive thirst, passing of large amounts of urine, increase in appetite and feeling weak) or family history of diabetes.
- Involuntary, irregular muscle movements, especially in the face.
- Past experience with excessive gambling.

Tell your doctor or health care provider:

- If you develop a high fever, muscle stiffness, very rapid heartbeat or altered mental status.
- If you are 65 years or older and are suffering from dementia (loss of memory and other abilities).
- If you notice any weight gain, develop unusual movements, any difficulty swallowing or allergy symptoms (see Possible side effects).
- If you or your family/caretaker notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours, such as addictive gambling, excessive eating or spending, an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose of ARIPIPRAZOLE KIARA.
- If you have been diagnosed with attention deficit hyperactivity disorder (ADHD) and are receiving treatment.

ARIPIPRAZOLE KIARA may cause sleepiness, fall in blood pressure when standing up, dizziness and changes in your ability to move and balance, which may lead to falls (see Possible side effects). Caution should be taken, particularly if you are over the age of 65 or have some debility.

Other medicines and ARIPIPRAZOLE KIARA

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

Tell your doctor or pharmacist before you take ARIPIPRAZOLE KIARA if you are using:

- Antihypertensive medicine (used to lower your blood pressure). ARIPIPRAZOLE KIARA may increase the effect of these medicines.
- Medicines to correct heart rhythm, including quinidine (used to treat an irregular heartbeat or malaria), amiodarone and flecainide.
- Fluoxetine, paroxetine (used to treat depression, anxiety and obsessive-compulsive disorder) or escitalopram (used to treat depression and anxiety).
- Ketoconazole or itraconazole (used to treat fungal infections).
- Protease inhibitors, efavirenz or nevirapine (used to treat Human Immunodeficiency Virus (HIV) infection).
- Diltiazem (used to treat chest pain).
- Phenytoin, phenobarbitone, primidone (used to treat seizures (fits)) or carbamazepine (used to treat seizures (fits) and some types of nerve pain).
- Rifampicin or rifabutin (used to treat tuberculosis (TB) infection).
- St. John’s Wort (herbal medicine used to treat mild depression).
- Medicines that increase the level of serotonin and other medicines used to treat depression, anxiety, obsessive-compulsive disorder and social phonia.
- Painkillers, such as tramadol to treat pain.
- Triptans, such as sumatriptan to treat migraine.
- Any medicines causing excessive tiredness.

These medicines may increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with ARIPIPRAZOLE KIARA, you should see your doctor or health care provider.

ARIPIPRAZOLE KIARA with food, drink and alcohol

ARIPIPRAZOLE KIARA can be taken regardless of meals.

The use of alcohol with ARIPIPRAZOLE KIARA should be avoided.

Pregnancy and breastfeeding

ARIPIPRAZOLE KIARA is not recommended for use during pregnancy and breastfeeding, as the safety has not been established.

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 health care provider for advice before taking ARIPIPRAZOLE KIARA.

Driving and using machines

Your ability to drive and use machines may be affected by side effects, such as tiredness, sleepiness, light-headedness, blurred and double vision. Do not drive a vehicle or operate machinery until you know how ARIPIPRAZOLE KIARA affects you.

ARIPIPRAZOLE KIARA contains lactose

ARIPIPRAZOLE KIARA contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take ARIPIPRAZOLE KIARA

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

Always take ARIPIPRAZOLE KIARA exactly as your doctor or pharmacist has told you. You

should check with your doctor or pharmacist if you are not sure.

The usual dose is 10 mg or 15 mg once per day. Your doctor may prescribe you a lower or higher dose to a maximum of 30 mg once per day.
Your doctor may prescribe you other medicines with ARIPIPRAZOLE KIARA.

Your doctor will decide your dose and tell you how long your treatment with ARIPIPRAZOLE KIARA will last. Do not stop treatment early because you feel better.
Do not stop taking ARIPIPRAZOLE KIARA unless your doctor tells you to do so. Even if you feel better, do not stop taking ARIPIPRAZOLE KIARA before you speak to your doctor first.
If you have the impression that the effect of ARIPIPRAZOLE KIARA is too strong or too weak, tell your doctor, pharmacist or health care provider.
Try to take ARIPIPRAZOLE KIARA at the same time each day.

If you take more ARIPIPRAZOLE KIARA than you should

In the event of overdosage, consult your doctor, pharmacist or health care provider without delay. If neither is available, contact the nearest hospital or poison centre.
Symptoms that may occur include a lack of energy, increased blood pressure, sleepiness, changes in the way your heart beats, nausea (feeling sick), vomiting (being sick) and diarrhoea.

If you forget to take or miss a dose of ARIPIPRAZOLE KIARA

If you forget to take a dose, take it as soon as you remember unless it is nearly time to take your next dose, then skip the missed dose and go back
to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

ARIPIPRAZOLE KIARA can have side effects.
Not all side effects reported for ARIPIPRAZOLE KIARA are included in this leaflet. Should your

general health worsen or if you experience any untoward effects while taking ARIPIPRAZOLE KIARA, please consult your health care provider for advice.

If any of the following happens, stop taking ARIPIPRAZOLE KIARA and tell your doctor, pharmacist or health care provider immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips and 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 allergic reaction to ARIPIPRAZOLE KIARA. You may need urgent medical attention or hospitalisation.

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

- High fever, irregular heartbeat, stiff muscles, sweating and altered mental status (called Neuroleptic malignant syndrome).
- Clumsiness, stiff muscles, dilated pupils, a rapid heartbeat and restlessness (called Serotonin syndrome).
- Easy or excessive bruising or bleeding of your skin, sometimes with pinpoint-sized reddish-purple spots.
- Signs of recurrent infections, such as fever, chills or sore throat.
- Seizures (fits).
- Fever, hallucinations, urinating more than usual, dry mouth, exessive thirst, fever and a warm, dry skin.
- Changes in the way your heart beats or heart attack.
- Extreme thirst, frequent urination, nausea (feeling sick) or vomiting (being sick), fruity-smelling breath and pain in your stomach area.

- Thoughts or attempt of harming or killing yourself.
- Pain, tenderness or swelling in your legs, skin that feels warm to the touch and a red colour or streaks on the skin.
- Rapid breathing, a rapid heart rate, shortness of breath and sudden, sharp chest pain.
- Yellowing of your skin and eyes, loss of appetite, sleepiness, pain and swelling in your stomach area, fever, nausea (feeling sick) and vomiting (being sick).
- Pain in your stomach area that radiates to your back, fever, nausea (feeling sick) and vomiting (being sick).

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

Tell your doctor, pharmacist or health care provider if you notice any of the following:

Frequent side effects:

- High blood sugar, urinating more than usual, weight loss, very dry skin and excessive thirst.
- Difficulty sleeping, feeling restless or anxious.
- Headache, dizziness, drowsiness or excessive tiredness.
- Tremor (shaking), involuntary muscle contractions, moving slowly, irregular movements or muscle stiffness.
- Blurred vision.
- Feeling dizzy or light-headed when standing or sitting up quickly.
- Nausea (feeling sick), vomiting (being sick), constipation, indigestion, stomach discomfort and having more saliva than usual.
- Lack of energy or feeling tired.

Less frequent side effects:

- Hyperprolactinaemia (causing irregular periods or menstrual flow, pain in breasts, loss of libido or production of breastmilk).
- Involuntary movements of the face, tongue, lips or jaw, hiccups or prolonged muscle contraction resulting in abnormal movements.

- Increase in blood sugar.
- Feeling depressed.
- Altered or increased sexual interest.
- Double vision.
- Swelling of your legs, arms, hands feet or ankles.

The following side effects have been reported with an unknown frequency:

- Abnormal muscle breakdown which may cause kidney problems or muscle pain.
- Changes in results when your doctor tests your blood for liver enzymes, sugar levels or enzymes indicating muscle damage.
- Accidental inhalation of food with risk of pneumonia (lung infection).
- Difficulty talking due to incapability to form certain sounds.
- Difficulty swallowing, spasms of the muscles around the voice box or in your throat.
- Prolonged and/or painful erection.
- Decreased sodium levels in the blood.
- Anorexia, decrease or increase in weight.
- Fixation of the eyeballs in one position.
- Increased blood pressure or chest pain.
- Skin rash, sensitivity to light, hair loss or excessive sweating.
- Difficulty controlling your bladder, such as involuntary loss of urine or difficulty passing urine.
- Withdrawal symptoms in newborn babies in case of exposure during pregnancy.
- Difficulty controlling your body temperature.
- Feeling agitated, aggressive or nervous.
- Inability to resist the impulse or temptation to perform an action that could be harmful to you or others, which may include: gambling excessively despite serious personal or family consequences, altered or increased sexual interest and behaviour of significant concern to you or to others (such as an increased sexual drive), uncontrollable excessive shopping, binge eating (eating large amounts of food in a short time period) or a tendency to wander away.

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 other health care provider. 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 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 ARIPIPRAZOLE KIARA.

5. How to store ARIPIPRAZOLE KIARA

- Store at or below 25 °C.
- Protect from moisture.
- Keep the blister strip in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ARIPIPRAZOLE KIARA contains

The active substance in ARIPIPRAZOLE KIARA is aripiprazole.

ARIPIPRAZOLE 5 KIARA: Each tablet contains 5 mg aripiprazole.

ARIPIPRAZOLE 10 KIARA: Each tablet contains 10 mg aripiprazole.

ARIPIPRAZOLE 15 KIARA: Each tablet contains 15 mg aripiprazole.

ARIPIPRAZOLE 30 KIARA: Each tablet contains 30 mg aripiprazole.

The other ingredients in ARIPIPRAZOLE 5 KIARA are hydroxypropyl cellulose (E463), lactose

monohydrate, magnesium stearate (E572), maize starch and microcrystalline cellulose (E460).

The other ingredients in ARIPIPRAZOLE 10, 15 and 30 KIARA are hydroxypropyl cellulose (E463), iron oxide red (E172), lactose monohydrate, magnesium stearate (E572), maize starch and microcrystalline cellulose (E460).

What ARIPIPRAZOLE KIARA looks like and contents of the pack

ARIPIPRAZOLE 5 KIARA: White to off-white, rounded off rectangular shaped, biconvex tablets debossed with “A5” on one side and plain on the other side.

ARIPIPRAZOLE 10 KIARA: Pink coloured, oval shaped, biconvex tablets debossed with “A10” on one side and plain on the other side.

ARIPIPRAZOLE 15 KIARA: Pink coloured, round, biconvex tablets debossed with “A15” on one side and plain on the other side.

ARIPIPRAZOLE 30 KIARA: Pink coloured, oval shaped, biconvex tablets debossed with “A30” on one side and plain on the other side.

ARIPIPRAZOLE KIARA is packed in OPA/Aluminium/PVC and aluminium blister strips packed in an cardboard carton.

Pack size: 10, 30, 60 or 100 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

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7551

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