PATIENT INFORMATION LEAFLET FOR APRIZON

TABLETS

SCHEDULING STATUS

S5

APRIZON 5 (Aripiprazole) Tablets

APRIZON 10 (Aripiprazole) Tablets

APRIZON 15 (Aripiprazole) Tablets

APRIZON 30 (Aripiprazole) Tablets

Read all of this leaflet carefully before you start taking APRIZON.

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

1. What APRIZON is and what it is used for

The active substance in APRIZON is aripiprazole.

APRIZON 5 tablets contains 5 mg of aripiprazole.

APRIZON 10 tablets contains 10 mg of aripiprazole.

APRIZON 15 tablets contains 15 mg of aripiprazole.

APRIZON 30 tablets contains 30 mg of aripiprazole.

APRIZON is one of a group of medicines called antipsychotics. APRIZON is used to treat symptoms of schizophrenia in adults. Schizophrenia is a condition, which is 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.

APRIZON is also used to treat adults who suffer from manic episodes in Bipolar I Disorder. Bipolar I Disorder is a condition with symptoms such as feeling very happy ("high"), having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability.

2. What you need to know before you take APRIZON

Do not take APRIZON

- If you are hypersensitive (allergic) to aripiprazole or any of the other ingredients of APRIZON.
- If you are younger than 18 years.

Warnings and precautions

- Tell your doctor immediately if you are having any thoughts or feelings about hurting yourself. Suicidal thoughts and behaviours have been reported during treatment with aripiprazole.
- If you have involuntary, irregular muscle movement, especially in the face.
- If you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heartbeat.
- If you are or will be exposed to situations where your body temperature may be increased, e.g. strenuous exercise, extreme heat exposure, dehydration or combination use with a medicine, which fall within the anticholinergic class.
- If you ever had seizures.
- If you suffer from cardiovascular disease (a history of heart attack, heart disease or other heart problems), have had a stroke or “mini “stroke or are exposed to conditions of low blood pressure (dehydration, low blood volume or treatment with blood pressure reducing medications).
- If you have a drop in blood pressure when getting up.
- If you are an elderly patient suffering from dementia (loss of memory and other mental abilities), as there is an increased risk of stroke or death.
- If you suffer from diabetes (high blood sugar, characterised by symptoms such as excessive thirst, passing of large amounts of urine, increase in appetite, and feeling weak) or are at risk for diabetes (family history of diabetes or obesity).
- If you have difficulty in swallowing.

- If you are at risk for a type of pneumonia called aspiration pneumonia.

Children and Adolescents: APRIZON should not be used by children and adolescents below the age of 18 years.

Other medicines and APRIZON

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

Blood pressure-lowering medicine: APRIZON may increase the effect of medicines used to lower the blood pressure.

If taking APRIZON with certain medicines, your dose of APRIZON may need to be changed. It is especially important to mention the following to your healthcare professional:

- Medicines to correct heart rhythm
- Medicines which may cause electrolyte imbalances in the blood
- Lithium
- Antidepressants or herbal remedies used to treat depression and anxiety
- Antifungal agents
- Certain medicines to treat HIV and AIDS
- Certain medicines used to treat TB
- Anticonvulsants used to treat epilepsy

Taking APRIZON with food and drink

- APRIZON can be taken regardless of meals.
- Alcohol should be avoided when taking APRIZON.

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 this APRIZON.

Safety of APRIZON in pregnancy and breastfeeding has not been established.

Newborn infants with mothers taking medicine for mental illness (including APRIZON) during pregnancy are at risk of adverse reactions including medicine-induced movement disorders and/or withdrawal symptoms that may vary in severity and duration following delivery. There have been reports of agitation, damage to the central nervous system (hypertonia), decreased muscle tone and strength that result in floppiness (hypotonia), involuntary, somewhat rhythmic, muscle contraction and relaxation (tremor), a state of strong desire for sleep, or sleeping for unusually long periods (somnolence), respiratory suffering, or feeding disorder. Consequently, newborn infants should be monitored carefully.

Driving and using machines

Do not drive or use any tools or machines, until you know how APRIZON affects you.

3. How to take APRIZON

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

Always take APRIZON exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended starting dose for adults is 10 mg or 15 mg once a day with a maintenance dose of 15 mg. However, your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

If you have the impression that the effect of APRIZON is too strong or too weak, tell your doctor or pharmacist.

If you take more APRIZON than you should

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

In the event of an overdose, you may experience the following signs and symptoms: lethargy (a feeling of weakness), increased blood pressure, drowsiness, increased heart rate, vomiting and loss of consciousness (blackouts).

If you forget to take APRIZON

Do not take a double dose to make up for forgotten individual doses.

If you forget to take a tablet, take it as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed tablet at all. Do not take two tablets at once to make up for the one you have missed.

Effects when treatment with APRIZON is stopped:

You are taking APRIZON to improve your mental health. If you stop taking APRIZON, your mental health may be negatively affected. You should not stop taking APRIZON, unless you have discussed it with your doctor or pharmacist.

4. Possible side effects

APRIZON can have side effects.

Not all side effects reported for APRIZON are included in this leaflet.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- yellow of the skin and eyes, also called jaundice**.**

These are very serious side effects. If you have them, you may have had a serious allergic reaction to **APRIZON**. 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:

- Chest pain
- Less urine than is normal for you, difficulty in passing urine, involuntary urination
- Changes in the way your heart beats, fast heart rate, feeling anxious

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

Tell your doctor if you notice any of the following:

- Restlessness (unable to sit or keep still), tremors, uncontrollable twitching or jerking movements
- Difficulties in sleeping, dizziness, drowsiness, headache
- Blurred vision
- Rapid fall in blood pressure when standing up (orthostatic hypotension)
- Constipation, indigestion, diarrhoea increased production of saliva, nausea, stomach discomfort, vomiting
- Tiredness and weakness
- Muscle stiffness
- Inflammation of the liver
- Inflammation of the pancreas
- Coma, diabetes, fluctuation of blood glucose, high blood sugar, ketones in the blood and urine,
- Convulsions (fits) or involuntary, repetitive body movements
- Pneumonia that develops due to inhalation of foreign materials (food, liquids saliva) into the lungs
- Feeling agitated (irritated)
- High blood pressure
- Difficulty controlling core body temperature, fever
- Loss of consciousness
- Prolonged and painful erection
- Uncontrolled urge to gamble
- Speech disorder
- Neuroleptic malignant syndrome (if you have stiff muscles, high temperature, confusion and other related symptoms)

- Loss of skeletal muscle, muscle and joint stiffness, muscle pain
- Anorexia, weight gain, weight loss
- Excessive sweating
- Abnormally low levels of blood platelets, low levels of neutrophils in the blood, low levels of white blood cells
- Low sodium level in the blood
- Increases of the following substances during blood testing: alanine aminotransferase (increased ALT or SGPT), aspartame aminotransferase (increased AST or SGOT), creatine phosphokinase, GGT, glycosylated haemoglobin
- Suicide, suicide attempt, thoughts of suicide

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. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

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

5. How to store APRIZON

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 25 °C in the original container.
- Keep well closed – HDPE bottles
- Keep blister in carton until required for use

6. Contents of the pack and other information

What APRIZON contains

The other ingredients are croscarmellose sodium, crystalline maltose, magnesium stearate, microcrystalline cellulose and pregelatinised starch.

APRIZON 5 tablets additionally contain: Indigo carmine (E132).

APRIZON 10 tablets additionally contain: Iron oxide red (E172).

APRIZON 15 tablets additionally contain: Iron oxide yellow (E172).

APRIZON 30 tablets additionally contain: Iron oxide red (E172).

Contains sugar: maltose

What APRIZON looks like and contents of the pack

APRIZON 5: Blue, round, biconvex tablets, marked with “5” on one side.

APRIZON 10: Pink, round, biconvex tablets, marked with “10” on one side.

APRIZON 15: Yellow, round, biconvex tablets, marked with “15” on one side

APRIZON 30: Pink, oval, biconvex tablets, marked with “30” on one side.

APRIZON tablets are available in PA/ALL/PVC – Aluminium foil blister (alu-alu blister) packs of 14, 28 or 98 tablets. Blisters are packed into cardboard cartons.

APRIZON tablets are available in white opaque High Density Polyethylene (HDPE) bottles with child resistant white polypropylene (PP) screw caps with mounted white low density polyethylene desiccant containing 14, 28 or 98 tablets. HDPE bottles are packed into cardboard cartons

Holder of certificate of registration

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