PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

Arizofy® 5 mg (tablets)

Arizofy® 10 mg (tablets)

Arizofy® 15 mg (tablets)

Arizofy® 20 mg (tablets)

Arizofy® 30 mg (tablets)

Aripiprazole

Each ARIZOFY 5 mg tablet contains sugar (lactose monohydrate 71,017 mg).

Each ARIZOFY 10 mg tablet contains sugar (lactose monohydrate 65,967 mg).

Each ARIZOFY 15 mg tablet contains sugar (lactose monohydrate 97,751 mg).

Each ARIZOFY 20 mg tablet contains sugar (lactose monohydrate 132,333 mg).

Each ARIZOFY 30 mg tablet contains sugar (lactose monohydrate 196,500 mg).

Read all of this leaflet carefully before you start taking ARIZOFY

- 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.
- ARIZOFY 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 ARIZOFY is and what it is used for

2. What you need to know before you take ARIZOFY

3. How to take ARIZOFY

4. Possible side effects

5. How to store ARIZOFY

6. Contents of the pack and other information

1. What ARIZOFY is and what it is used for

ARIZOFY contains the active substance aripiprazole and belongs to a group of medicines called antipsychotics.

ARIZOFY 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.

ARIZOFY is also 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 ARIZOFY.

2. What you need to know before you take ARIZOFY

Do not take ARIZOFY:

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

Warnings and precautions

Take special care with ARIZOFY:

Tell your doctor if you suffer from:

- High blood sugar (characterised by symptoms such as excessive thirst, passing large amounts of urine, increased appetite and feeling weak) or if you have a family history of diabetes
- Epilepsy (fits/seizures)
- Involuntary, irregular muscle movements, especially in the face
- Heart diseases, family history of heart disease, stroke or abnormal blood pressure
- Known low blood pressure
- Blood clots or family history of blood clots, as antipsychotics have been associated with formation of blood clots
- Dizziness or light-headedness

If you notice an increase in your body weight, experience any difficulty in swallowing or allergic symptoms, please inform your doctor immediately.

If you are an elderly person suffering from dementia (loss of memory and other mental abilities), you should tell your doctor.

If you are an elderly person suffering from Alzheimer's disease (form of dementia) and have had stroke or reduced blood flow to the brain, you should tell your doctor.

Tell your doctor immediately if you are having thoughts or feelings about hurting yourself. Suicidal thoughts and behaviours have been reported during treatment with aripiprazole, the active ingredient in ARIZOFY.

Tell your doctor immediately if you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status, or fast or irregular heartbeat (also known as Neuroleptic Malignant Syndrome).

Tell your doctor if you or your family/carer 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. If this happens, your doctor may need to reduce dose or stop your treatment with ARIZOFY.

Tell your doctor If you are taking medication for attention deficit hyperactivity disorder (ADHD).

Tell your doctor if you are experiencing problems with your body temperature, where it feels like you are overheating.

Children and adolescents

ARIZOFY is contraindicated in patients under 18 years of age.

Other medicines and ARIZOFY

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

ARIZOFY may increase the effect of medicines used to lower the blood pressure. Tell your doctor if you take medicines to keep your blood pressure under control.

Medicines that increase the level of serotonin, may increase the risk of side effects when taken together with ARIZOFY. Such medicines include triptans (such as sumatriptan and rizatriptan for migraine), tramadol (for pain), tryptophan (for depression), SSRIs (such as paroxetine and fluoxetine), tricyclics (such as clomipramine, amitriptyline), pethidine, St John's Wort (used as a herbal remedy for mild depression) and venlafaxine. These medicines increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with ARIZOFY, you should see your doctor.

Taking ARIZOFY with some medicines may mean your doctor will need to change your dose of ARIZOFY or the other medicines. It is especially important to mention the following medicines to your doctor:

- Antihypertensive medicines (used in the treatment of high blood pressure)
- Carbamazepine, phenytoin, phenobarbital or primidone (used to treat epilepsy/fits), as your doctor may consider increasing your ARIZOFY dose
- Quinidine (used to correct heart rhythm)
- Ketoconazole or itraconazole (used to treat fungal infections)
- Protease inhibitors, efavirenz or nevirapine (used to treat HIV infection (AIDS))
- Diltiazem (used in heart disorders)
- Escitalopram, fluoxetine or paroxetine (used to treat depression and generalised anxiety disorder)
- Rifampicin, rifabutin (used to treat tuberculosis (TB))
- St. John's wort (herbal remedy used to treat depression)
- Warfarin (used to prevent the forming of blood clots)

ARIZOFY with food, drink and alcohol

ARIZOFY may be taken with or without food.

Alcohol intake should be avoided when taking ARIZOFY.

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 health care provider for advice before taking ARIZOFY.

You should not take ARIZOFY if you are pregnant.

ARIZOFY is excreted in breastmilk. You doctor will decide whether you need to stop breastfeeding whilst taking ARIZOFY or whether you should stop ARIZOFY whilst breastfeeding.

The following symptoms may occur in new-born babies, of mothers that have used ARIZOFY in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and feeding difficulties. If your baby develops any of these symptoms you should contact your doctor.

Driving and using machines

ARIZOFY may impair your ability to drive and use machinery. Dizziness, vision problems, sleepiness and fainting may occur during treatment with ARIZOFY. Do not drive, operate machinery, or do anything else that require your attention until you know how ARIZOFY affects you.

ARIZOFY contains lactose

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ARIZOFY.

ARIZOFY contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

3. How to take ARIZOFY

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

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

The usual dose is 15 mg per day. 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 ARIZOFY is too strong or too weak, talk to your doctor or pharmacist.

If you take more ARIZOFY than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining tablets with you, so that the doctor or the pharmacist knows what you have taken.

If you forget to take ARIZOFY

If you have missed your dose, take the next dose as usual just before the next meal. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ARIZOFY

Do not stop your treatment just because you feel better. It is important that you carry on taking ARIZOFY for as long as your doctor has instructed you.

4. Possible side effects

ARIZOFY can have side effects.

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

Stop taking ARIZOFY and seek medical help if you have any of these signs of an allergic reaction:

- Swelling of your face, lips, mouth, tongue, eyes or throat (angioedema)
- Difficulty breathing, dizziness (severe hypersensitivity)

These are symptoms of serious reaction which must be treated immediately, usually in a hospital.

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

- Changes in the levels of some blood cells (confirmed by a blood test)
- Unusual heartbeat
- Allergic reaction (e.g., swelling in the mouth, tongue, face and throat, itching, rash)
- Combination of fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate, fainting (neuroleptic malignant syndrome)

- High blood sugar, onset or worsening of diabetes, ketoacidosis (ketones in the blood and urine) or coma
- Reduced sodium level in the blood (confirmed by a blood test); weight gain, weight loss, anorexia
- Nervousness, agitation, excessive gambling, thoughts of suicide, suicide attempt and suicide
- Speech disorder
- Seizure (fit)
- Reduced consciousness and sudden changes in blood pressure and heart rate; fainting, high blood pressure, blood clots in the veins especially in the legs
- Spasm of the muscles around the voice box
- Inflammation of the pancreas; liver failure, inflammation of the liver, yellowing of the skin and white part of eyes, reports of abnormal liver test values, abdominal and stomach discomfort, diarrhoea
- Skin rash and sensitivity to light
- Unusual hair loss or thinning
- Involuntary loss of urine, difficulty in passing urine
- Prolonged and/or painful erection

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

Side effects that may occur frequently include:

- Restlessness, anxiety, difficulty in sleeping
- Headache
- Dizziness, light-headedness, or fainting, particularly when standing up
- Trembling or shaking
- Sleepiness

- Feeling restless and unable to keep still, difficulty sitting still
- Uncontrollable twitching, jerking or writhing movements, restless legs
- Blurred vision
- Fast irregular heartbeat
- Nausea, vomiting, constipation, heartburn, increased production of saliva
- Unusual weakness or tiredness

Side effects that may occur less frequently include:

- Increased or decreased blood levels of the hormone prolactin in the blood (confirmed by a blood test)
- Feeling depressed
- Altered or increased sexual interest
- Irregular muscle movements (especially of the face)
- Muscle disorder causing twisting movements (dystonia)
- Double vision
- Hiccups

The frequency of the following side effects is unknown:

- Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others
- Binge eating (eating large amounts of food in a short time period)
- Uncontrollable excessive shopping
- A tendency to wander away
- Aggression
- Serotonin syndrome (a reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles)

- Fixation of the eyeballs in one position
- Life-threatening irregular heartbeat
- Sudden unexplained death
- Heart attack
- Slower heartbeat
- High blood pressure
- Accidental inhalation of food with risk of pneumonia (lung infection)
- Difficulty swallowing
- Excessive sweating
- Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia)
- Abnormal muscle breakdown which can lead to kidney problems
- Muscle pain
- Stiffness
- Withdrawal symptoms in new-born babies in case of exposure during pregnancy
- Difficulty controlling core body temperature or feeling of overheating
- Chest pain
- Swelling of hands, ankles, or feet
- In blood tests: increased or fluctuating blood sugar, increased glycosylated haemoglobin, increased creatine phosphokinase

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 "**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 ARIZOFY.

Suspected side effects can also be reported directly to the HCR via the link: pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store ARIZOFY

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Store at or below 25 °C. Do not remove from outer carton until required for use.
- Do not use after the expiry date printed on the blister or 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 ARIZOFY contains

The active substance is aripiprazole.

The other substances are hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, maize starch and microcrystalline cellulose.

ARIZOFY 5 mg: Aluminium lake (FD & C blue no. 2 aluminium lake) and indigo carmin (E132)

ARIZOFY 10 mg & 30 mg: Iron oxide red (E172)

ARIZOFY 15 mg: Iron oxide yellow (E172)

What ARIZOFY looks like and contents of the pack

ARIZOFY 5 mg: Blue coloured, mottled, round shaped tablets, debossed with 'SZ' on one side and '444' on the other side.

ARIZOFY 10 mg: Pink coloured, mottled, round shaped tablets debossed with ‘SZ’ on one side and ‘446’ on the other side.

ARIZOFY 15 mg: Yellow coloured, mottled, round shaped tablets debossed with ‘SZ’ on one side and ‘447’ on the other side.

ARIZOFY 20 mg: White coloured, round shaped tablets debossed with ‘SZ’ on one side and ‘448’ on the other side.

ARIZOFY 30 mg: Pink coloured, mottled, round shaped tablets debossed with ‘SZ’ on one side and ‘449’ on the other side.

ARIZOFY 5 mg: Aluminium/aluminium foil blister packs containing 10 tablets.

ARIZOFY 10 mg: Aluminium/aluminium foil blister packs containing 10 tablets.

ARIZOFY 15 mg: Aluminium/aluminium foil blister packs containing 10 tablets.

ARIZOFY 20 mg: Aluminium/aluminium foil blister packs containing 10 tablets.

ARIZOFY 30 mg: Aluminium/aluminium foil blister packs containing 10 tablets.

The blister packs are packed into an outer cardboard carton containing 30 tablets.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

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ARIZOFY 5 mg: 46/2.6.5/0874

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ARIZOFY 15 mg: 46/2.6.5/0876

ARIZOFY 20 mg: 46/2.6.5/0877

ARIZOFY 30 mg: 46/2.6.5/0878

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07