PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only.

Aripiprazole Sandoz® 5
Aripiprazole Sandoz® 10
Aripiprazole Sandoz® 15
Aripiprazole Sandoz® 30

Tablets

Composition:
Aripiprazole Sandoz 5: Each tablet contains: aripiprazole 5 mg
Aripiprazole Sandoz 10: Each tablet contains: aripiprazole 10 mg
Aripiprazole Sandoz 15: Each tablet contains: aripiprazole 15 mg
Aripiprazole Sandoz 30: Each tablet contains: aripiprazole 30 mg
Inactive and allergenic ingredients in this medicine – see in section 2 under "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, contact the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Elderly patients with dementia-related psychosis treated with antipsychotics are at high risk of death. Aripiprazole Sandoz is not intended for the treatment of dementia-related psychosis.
Antidepressants increase the risk of suicidal thoughts in children, adolescents and young adults up to the age of 25.
When starting treatment with the medicine, patients of all ages and their relatives must monitor for behavioral changes, such as worsening of depression, suicidal thoughts, aggressiveness and the like (see in section 2 "Special warnings regarding use of the medicine").

1. What is the medicine intended for?

Aripiprazole Sandoz 5, 10, 15, 30 are intended:
- For treatment of schizophrenia.
- For treatment of moderate to severe manic episodes in bipolar disorder type 1 and for the prevention of new manic episodes in patients who experience predominantly manic episodes and who had previous manic episodes that responded to aripiprazole treatment.

In addition, Aripiprazole Sandoz 5, 10, 15 are intended:
- For combined treatment of clinical depression (major depressive disorder [MDD]) for patients who experienced a partial response to therapy with antidepressants.
- For treatment of irritability associated with autistic disorder in children (ages 6-17 years).

Therapeutic group: Atypical antipsychotics.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients in this medicine (see section 6 "Further information").

Special warnings regarding use of the medicine
Before treatment with Aripiprazole Sandoz, tell the doctor if:
- You are pregnant or planning to become pregnant, breastfeeding or planning to breastfeed.
- You suffer from a high blood sugar level (characterized by symptoms such as increased thirst, passing large amounts of urine, increased appetite and weakness) or a family history of diabetes.
- You suffer from epileptic attacks (seizures).
- You suffer from uncontrolled and irregular muscle movements.
- You suffer from cardiovascular diseases (heart and blood vessels), a family history of cardiovascular diseases.
- You had a stroke or "mini" stroke.
- You suffered in the past from gambling addiction.
- You recently experienced weight gain, difficulty swallowing or allergic reactions, involuntary movements, sleepiness that interferes with daily activities.
- You are an elderly patient suffering from dementia (loss of memory and other cognitive capacities); you or your caregiver must tell your doctor if you had a stroke or a "mini" stroke.
- You suffer, or have suffered in the past from depression.
- You suffer from bipolar disorder.
- You have high blood fat levels.
- You suffer from high or low blood pressure.
- You have a history of falls or you are suffering from diseases or are taking medicines that can cause falls.
- You suffered from leukopenia or neutropenia as a result of taking medicines. Your doctor may want to have you perform extensive blood tests.
- You perform strenuous physical activity, are exposed to high temperatures, suffer from dehydration or regularly take medicines with anticholinergic activity.
- Inform your doctor immediately if you have suicidal thoughts or thoughts about self-injury (see the warning at the top of the leaflet and later in this section "Special warnings regarding use of the medicine").

Do not use this medicine for any purpose other than that for which it was prescribed.

Children and adolescents
This medicine is not intended for use in children and adolescents below the age of 6.
Antidepressants increase the risk of suicidal thoughts in children, adolescents and young adults. Closely monitor for behavioral changes, worsening or increase in suicidal thoughts and behavior.

Tests and follow-up
During treatment with Aripiprazole Sandoz, there may be a drop in blood pressure. You should therefore be under medical supervision and regularly monitor your blood pressure.
In addition, the doctor may refer you for blood tests for follow-up.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:
- Medicines to treat hypertension – Aripiprazole Sandoz may increase the effect of these medicines.

The following medicines may reduce the effect of Aripiprazole Sandoz:
- Medicines for treatment of fungal infections (itraconazole).
- Antibiotic – clarithromycin.
- Medicine for heart rhythm disturbances – quinidine.
- Antidepressants (from the SSRI family) – fluoxetine, paroxetine.

The following medicines may increase the effect of Aripiprazole Sandoz:
- Medicine for the treatment of epilepsy – carbamazepine.
- Antibiotic for the treatment of tuberculosis – rifampicin.
- Hypnotics – benzodiazepines, e.g., lorazepam.

Use of the medicine and food
The medicine can be taken with or without food.

Use of the medicine and alcohol consumption
Do not drink wines or alcoholic beverages while under treatment with the medicine.

Pregnancy, breastfeeding and fertility
Pregnancy
Do not use the medicine if you are planning to become pregnant or are pregnant, unless you have consulted with your doctor and discussed with him the risks versus the benefits of taking this medicine. Use of this medicine may affect the general condition of your baby.
You must report immediately to the doctor if you are pregnant, think you are pregnant or if you are planning to become pregnant.
Do not stop treatment on your own; consult with the doctor.
If you are in the third trimester of your pregnancy and have taken the medicine, you should be aware that the following effects may occur in your infant immediately upon birth: tremor, muscle stiffness/weakness, sleepiness, nervousness, difficulty breathing and difficulty in feeding.
If your baby suffers from any of these effects – contact the doctor immediately.
Use of Aripiprazole Sandoz when breastfeeding
Consult your doctor about the benefit versus side effects to the newborn if taking aripiprazole when breastfeeding. Consult the doctor about the best way to feed your baby when taking Aripiprazole Sandoz.

Driving and operating machinery
Use of this medicine may impair alertness and therefore, do not drive or operate dangerous machinery or engage in activities that require alertness until you know how this medicine affects you.
Children should be warned against riding bicycles or playing near the road.

Additional warnings
Avoid getting overheated and dehydrated. Avoid excessively strenuous physical activity. In hot weather, stay in a cool place, if possible. Avoid exposure to the sun. Avoid overdressing and thick clothing. Drink plenty of water.

Important information about some of the ingredients of the medicine
Aripiprazole Sandoz tablets contain lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product (also see section 6 "Further information").

3. How should you use the medicine?

Always use the medicinal product according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicinal product.
Only your doctor will determine your dosage and how you should take this medicine.
The usual dosage is:
Adults:
Schizophrenia and bipolar disorder: The usual dosage for adults is 15 mg, once a day. However, the doctor may prescribe a lower or higher dosage for you, up to a maximum of 30 mg once a day.
For adolescents 15 years of age and older, at the beginning of treatment, Aripiprazole Sandoz may be given in lower dosages, with a gradual increase up to the usual dosage of 10 mg once a day. However, the doctor may prescribe a lower or higher dosage for you, up to a maximum of 30 mg once a day.
Complementary treatment in major depressive disorder: The usual starting dosage is 2.5 **(another medicine containing aripiprazole may be used to achieve this dosage)** to 5 mg a day.
If necessary, the doctor may increase the dosage gradually.
Treatment of irritability associated with autistic disorder in children: The usual starting dosage is 2.5 mg a day **(another medicine containing aripiprazole may be used to achieve this dosage)**. The doctor will gradually increase the dosage to 5 to 15 mg a day, in accordance with the individual response to the medicine.
If you feel that the effect of the medicine is too strong or too weak, consult the doctor or pharmacist.

Do not exceed the recommended dose.
Swallow the medicine with water. Do not crush/split/chew the tablet.
Try to take the medicine at fixed times each day.

If you accidentally take a higher dosage of Aripiprazole Sandoz
Side effects that have been reported on overdosing with aripiprazole include vomiting, sleepiness and tremor.
Additional side effects that have been reported included high acid concentrations in the blood (acidosis); aggressiveness; increased aspartate aminotransferase (AST) enzyme concentration in the blood, indicative of damage to the heart muscle or liver; atrial fibrillation; slow heart rate (bradycardia); coma, confusion; seizures; increased concentration of the creatine phosphokinase (CPK) enzyme, indicative of muscle damage, including to the heart muscle; reduced consciousness; high or low blood pressure.
Low blood potassium level (hypokalemia), prolonged QT interval, prolonged QRS complex, lung inflammation due to involuntary inhalation of food into the trachea, respiratory failure, repeated seizures without regaining consciousness in between (status epilepticus).
If you took an overdose or if you experience one or more of the listed symptoms, or if a child has accidentally swallowed the medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine at the required time, do not take a double dose to compensate for the forgotten dose. Take the next dose at the usual time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, use of Aripiprazole Sandoz may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

If you experience one or more of the following side effects, stop taking Aripiprazole Sandoz and tell your doctor immediately:
- New onset or worsened depression; suicidal thoughts; suicide attempt; new onset or worsened anxiety; restlessness or nervousness; sense of panic; sleeping difficulties; agitation; anger; aggressiveness; dangerously impulsive behavior; hyperactivity and excessive talkativeness (mania); behavioral changes.
- Cerebral event, including stroke.
- Neuroleptic malignant syndrome (NMS), whose symptoms are high fever exceeding 41°C, muscle stiffness, change in mental state, physiological instability (unusual heart rate, increased blood pressure, rapid heart rate or irregular heart rhythm). Additional signs: increased creatine phosphokinase (CPK), an enzyme whose level in the blood increases in direct proportion to muscle damage, including the heart muscle, myoglobin in the urine (myoglobinuria), which may indicate muscle breakdown (rhabdomyolysis), acute kidney failure.
- Increased blood sugar (hyperglycemia), diabetes. The following symptoms are indicative of high blood sugar level: thirst, need to urinate more frequently than usual, strong feeling of hunger, feeling of weakness and tiredness, abdominal pain, confusion, fruity-smelling breath.

Additional side effects
Common side effects (effects that occur in 1-10 in 100 users):
● Weakness; exhaustion; lack of energy ● Weight loss; loss of appetite ● Decrease in prolactin blood levels ● Twitching or involuntary movements; need to constantly be in motion ● Vomiting; nausea; stomach discomfort; constipation ● Dizziness, headaches; sleeping difficulties, anxiety and feeling of restlessness; blurred vision ● Upper respiratory tract diseases.

Uncommon side effects (effects that occur in 1-10 in 1,000 users):
● Slow heart rate, fast heart rate (palpitations) ● Edema in the limbs, swelling of the hands, ankles and legs ● Chest pains ● Falls ● Increased liver enzymes in blood tests ● Increased blood sugar (glucose) levels ● Increased concentration of the lactate dehydrogenase enzyme; increased levels of the gamma-glutamyl transpeptidase (GGT) enzyme ● Muscle weakness; muscle spasms; parkinsonism; memory loss; muscle stiffness; slow movement; partial or full loss of muscle movement; muscle rigidity; tremor; reduced motility; oculogyric crisis ● Aggressiveness; loss of sexual desire; hallucinations; impotence ● Nasal congestion; shortness of breath ● Skin rash; excessive sweating; itching; hair loss; photosensitivity ● Sharp drop in blood pressure when suddenly transitioning from a lying to sitting or standing position (orthostatic hypotension), which can cause dizziness and fainting ● Blood pressure increase or decrease.

Rare side effects (effects that occur in 1-10 in 10,000 users):
● Thrombocytopenia (decreased platelet levels in the blood) ● Atrial flutter; respiratory arrest; atrioventricular block; atrial fibrillation; angina pectoris; insufficient blood circulation to the heart muscle (myocardial ischemia); heart attack; heart failure ● Double vision ● Gastro-esophageal reflux ● Facial edema; urticaria ● Hepatitis; jaundice ● Hypersensitivity of the immune system ● Heat stroke ● Increased levels of prolactin, urea, bilirubin or creatinine in the blood; prolonged QT interval; increased hemoglobin A1C levels ● Low blood potassium level (hypokalemia); low blood sodium level (hyponatremia) ● Muscle cell breakdown (rhabdomyolysis); reduced motility (akinesia); muscle spasm that lasts for a split second and causes a sharp, short and very sudden unwanted movement (myoclonus); impaired coordination (nerve-muscle coordination); speech disturbances; convulsions ● Increased sex drive; inability to reach an orgasm ● Tics; suicidal thoughts; irresponsiveness to the surroundings (catatonia); sleepwalking ● Urinary retention; bedwetting ● Enlarged breasts in men; irregular menstruation; absence or termination of menstruation, breast pains; prolonged erection.

Side effects of unknown frequency (effects whose frequency has not yet been determined):
● Increased blood fat levels (dyslipidemia); weight gain ● Lack of impulse control when taking aripiprazole, especially compulsive gambling ● Changes in the level of certain blood cells (leukopenia – a low number of white blood cells, neutropenia – a low number of neutrophils) ● Fits ● Impaired judgement; impaired mental ability or motor skills; exhaustion and inability to communicate ● Difficulty regulating body temperature or overheating ● Swallowing difficulty; involuntary inhalation of food into the airways, with risk of lung inflammation.

In elderly patients with dementia, more cases of death during the course of treatment with this medicine were reported. In addition, cases of stroke or "mini" stroke have been reported.

Additional side effects in children and adolescents
Most of the side effects observed in children ages 6-18 have also been observed in adults.
Common side effects – increased blood insulin levels; wetting (mainly at night); drowsiness; headaches; vomiting; tiredness, increased or decreased appetite; excessive salivation and increased secretion of saliva; sleeplessness; nausea; nasal congestion; common cold; weight gain; involuntary twitching and movements; restlessness; tremor; muscle stiffness.
Uncommon side effects – dry mouth, involuntary tongue spasm; ocular freeze that can last for minutes or hours, in which the eyes are fixated to the sides or upward; sleep talking; excessive hairiness.

If a side effects occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. How should the medicine be stored?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions: Do not store above 30˚C.

6. Further information

In addition to the active ingredient, the medicine also contains:

Aripiprazole Sandoz 5:
lactose monohydrate; maize starch; microcrystalline cellulose; magnesium stearate; hydroxypropyl cellulose; indigo carmine (E132) aluminium lake.
Each **Aripiprazole Sandoz 5** tablet contains 71.02 mg lactose monohydrate.

Aripiprazole Sandoz 10:
lactose monohydrate; maize starch; microcrystalline cellulose; magnesium stearate; hydroxypropyl cellulose; iron oxide red (E172).
Each **Aripiprazole Sandoz 10** tablet contains 65.97 mg lactose monohydrate.

Aripiprazole Sandoz 15:
lactose monohydrate; maize starch; microcrystalline cellulose; magnesium stearate; hydroxypropyl cellulose; iron oxide yellow (E172).
Each **Aripiprazole Sandoz 15** tablet contains 97.75 mg lactose monohydrate.

Aripiprazole Sandoz 30:
lactose monohydrate; maize starch; microcrystalline cellulose; magnesium stearate; hydroxypropyl cellulose; iron oxide red (E172).
Each **Aripiprazole Sandoz 30** tablet contains 196.50 mg lactose monohydrate.

What the medicine looks like and contents of the package:
Aripiprazole Sandoz is packed in blister trays, which are inserted into a carton package. Each pack contains 30 tablets.

Aripiprazole Sandoz 5 tablets are round and blue, with "SZ" indicated on one side and "444" on the other.
Aripiprazole Sandoz 10 tablets are round and pink, with "SZ" indicated on one side and "446" on the other.
Aripiprazole Sandoz 15 tablets are round and yellow, with "SZ" indicated on one side and "447" on the other.
Aripiprazole Sandoz 30 tablets are round and pink, with "SZ" indicated on one side and "449" on the other.

License holder and importer's name and address:
Sandoz Pharmaceuticals Israel Ltd., P.O.Box 9015, Tel Aviv, Israel.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Aripiprazole Sandoz 5: 162-95-35898-00/01
Aripiprazole Sandoz 10: 162-96-35899-00/01
Aripiprazole Sandoz 15: 162-97-35911-00/01
Aripiprazole Sandoz 30: 162-99-35971-00/01