Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

It is advisable to have a person close to you read this leaflet.

Aripiprazole Sandoz® 5

Aripiprazole Sandoz® 10

Aripiprazole Sandoz® 15

Aripiprazole Sandoz® 30

Tablets

Active ingredient and its quantity:

Each tablet of **Aripiprazole Sandoz** 5 contains aripiprazole 5 mg, and also contains 71.02 mg lactose monohydrate.

Each tablet of **Aripiprazole Sandoz** 10 contains aripiprazole 10 mg, and also contains 65.97 mg lactose monohydrate.

Each tablet of **Aripiprazole Sandoz** 15 contains aripiprazole 15 mg, and also contains 97.75 mg lactose monohydrate.

Each tablet of **Aripiprazole Sandoz** 30 contains aripiprazole 30 mg, and also contains 196.50 mg lactose monohydrate.

For the list of inactive ingredients and allergens, please see section "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

The medicine is not intended for children below the age of 6.

1. What is Aripiprazole Sandoz intended for?

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

In addition, **Aripiprazole Sandoz** 5, 10, 15 are intended:

For combined treatment of major depressive disorder (MDD) in patients who experienced a partial response to treatment with antidepressants.

For treatment of irritability associated with autistic disorder in children (aged 6-17 years).

Therapeutic group: Atypical antipsychotics.

2. Before using Aripiprazole Sandoz

Do not use this medicine if:

- you are sensitive (allergic) to aripiprazole or to any of the other ingredients contained in the medicine (see Section 6: “Additional information”).

Special warnings about using Aripiprazole Sandoz
Before using Aripiprazole Sandoz, tell your doctor if:

- you have suicidal thoughts, thoughts about self injury, tell your doctor immediately, since suicidal thoughts and behavior have been reported during the course of treatment with aripiprazole.
- 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 seizures, since your doctor may want to monitor your condition more closely.
- you suffer from uncontrolled and irregular muscle movements, particularly in the facial area.
- you suffer from cardiovascular diseases (heart and blood vessels), a family history of cardiovascular diseases, abnormal blood pressure, a stroke or a transient ischemic attack (a “mini” stroke).
- you suffer from blood clots or a family history of blood clots, as there is an association between antipsychotics and formation of blood clots.
- you have suffered from gambling addiction in the past.

Tell your doctor if you have noticed weight gain, if you experience difficulty swallowing or allergic reactions, involuntary movements, sleepiness that interferes with daily activities.

If 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 transient ischemic attack (a “mini” stroke).

Tell your doctor immediately if you suffer from muscle stiffness or lack of flexibility accompanied by fever, excessive sweating, change in mental state or irregular or increased heart rate.

Tell your doctor if your family/caregiver notices that you are experiencing urges or cravings to abnormal behavior, or if you cannot resist the impulses to carry out certain activities that could harm yourself or others. These are called “impulse control disorders” and can include behaviors such as addictive gambling, excessive eating or spending, an abnormal sex drive or preoccupation with an increase in sexual thoughts or feelings.

Your doctor may adjust your dose or instruct you to stop using the medicine.

Aripiprazole Sandoz 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. Caution should be taken, particularly if you are elderly or have some debility.

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

Tests and follow up
During treatment with this medicine, there may be a drop in blood pressure. You should therefore be under medical supervision and regularly monitor your blood pressure.

Children and adolescents
This medicine is not intended for use in children below the age of 6.

Drug interactions
If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, tell your doctor or pharmacist. Especially if you are taking:

- medicines to treat hypertension: **Aripiprazole Sandoz** may increase the effect of these medicines.
- medicines for treatment of heart rhythm disorders (such as quinidine, amiodarone, flecainide), medicines and nutritional supplements for treatment of depression and anxiety (such as fluoxetine, paroxetine, venlafaxine, St. John's Wort), medicines for treatment of fungal infections (such as ketoconazole, itraconazole), certain medicines for treatment of HIV infection (such as efavirenz, nevirapine, protease inhibitors e.g. indinavir, ritonavir), medicines for treatment of epilepsy (such as carbamazepine, phenytoin, phenobarbital), certain antibiotics for treatment of tuberculosis (rifabutin, rifampicin) – these medicines may increase the risk of side effects or reduce the effect of **Aripiprazole Sandoz**. If you experience any unusual symptoms while using these medicines together with **Aripiprazole Sandoz**, you should contact your doctor.
- medicines that increase the level of serotonin: triptans (such as sumatriptan and zolmitripitan) used to treat migraines, tramadol (to treat pain), tryptophan, SSRI-type antidepressants (such as paroxetine and fluoxetine), tricyclic antidepressants (such as clomipramine and amitriptyline), pethidine (to relieve pain), hypericum (St. John's Wort), and venlafaxine. These medicines may increase the risk of side effects. If you experience any unusual symptoms while using these medicines together with **Aripiprazole Sandoz**, you should contact your doctor.

Using this medicine and food
The medicine can be taken with or without food.

Using Aripiprazole Sandoz and alcohol consumption
Do not drink wines or alcoholic beverages during the period of treatment with the medicine.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, or are planning to become pregnant, ask your doctor for advice before taking this medicine.

The following effects may occur in newborn babies of women who have used the medicine in the last trimester (last three months of pregnancy): tremor, muscle stiffness and/or weakness,

sleepiness, nervousness, difficulty breathing and difficulty in feeding. If your baby suffers from any of these effects – contact the doctor immediately.

If you are taking **Aripiprazole Sandoz**, ask your doctor about whether you should breastfeed your baby, considering the benefit to you of your therapy and the benefit to your baby of breastfeeding. Do not breastfeed during the course of treatment with the medicine. Consult your doctor about the best way to feed your baby during treatment with this medicine.

Driving and using machines
Use of this medicine may impair alertness and cause dizziness and vision problems; therefore, do not drive or operate dangerous machines or engage in activities requiring alertness until you know how this medicine affects you.

Important information about some of this medicine's ingredients
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

3. How to use Aripiprazole Sandoz?
Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.
The recommended dosage is usually:
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.

Combined treatment in major depressive disorder: The usual starting dosage is 2.5 mg (another medicine containing aripiprazole may be used to achieve this dosage) up 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 up to 15 mg a day, in accordance with each patient's 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 have accidentally taken a higher dose
Patients who have taken an overdose of the medicine have reported the following symptoms:
- rapid heartbeat, agitation/aggressiveness, problems with speech.

- unusual movements (especially in the facial area or tongue) and reduced level of consciousness.

Additional symptoms including:

- acute confusion, seizures (epilepsy), coma, a combination of fever, fast breathing, sweating.
- muscle stiffness, drowsiness or sleepiness, slow breathing, choking, high or low blood pressure, abnormal heart rhythm.

If you have accidentally taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you**.**

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

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using **Aripiprazole Sandoz** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Common side effects (occurring in 1-10 in 100 users):
Diabetes, involuntary twitching or movements, headache, tiredness, vomiting, nausea, an uncomfortable feeling in the stomach, constipation, increased secretion of saliva, light-headedness, difficulty sleeping, anxiety and feeling of agitation, difficulty standing or sitting still, akathisia (an uncomfortable inner feeling of restlessness and a compelling need to move constantly), sleepiness, tremor, blurred vision.

Uncommon side effects (occurring in 1-10 in 1,000 users):
Excessive secretion of the hormone prolactin; high blood sugar levels; altered or increased sexual interest; involuntary movements of the mouth, tongue and limbs (tardive dyskinesia); muscle disorder causing twisting movements (dystonia); restless legs; a fall in blood pressure on standing up which may cause dizziness or fainting; rapid heartbeat; double vision; eye sensitivity to light; depression; hiccups.

Side effects of unknown frequency (the frequency of these effects has not been established yet): low levels of white blood cells; low levels of blood platelets; allergic reaction (e.g., swelling of the mouth, tongue, face and throat, itching, rash); onset of diabetes or worsening of preexisting diabetes, diabetic ketoacidosis (ketones in the blood and urine) or coma; high blood sugar level; low sodium level in the blood; loss of appetite (anorexia); weight loss; weight gain; suicidal thoughts, suicide attempts and suicide; sensation of aggressiveness; restlessness; nervousness; neuroleptic malignant syndrome (NMS), a syndrome which is a combination of symptoms e.g., fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate; seizures; serotonin syndrome (characterized by an exaggerated

feeling of happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles); speech disorders; fixation of the eyeballs in one position; sudden unexplained death; life-threatening irregular heartbeat; heart attack; slower heartbeat; blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel from the veins to the lungs causing chest pain and difficulty breathing (if you notice these symptoms, contact the doctor immediately); high blood pressure; fainting; accidental inhalation of food into the respiratory tract with risk of pneumonia; muscle spasms around the vocal chords; inflammation of the pancreas; difficulty swallowing; diarrhea; abdominal discomfort; stomach discomfort; liver failure; inflammation of the liver; yellowing of the skin and eyes; abnormal levels of liver enzymes; skin rash; skin sensitivity to light; baldness; excessive sweating; serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome). This syndrome appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high fever, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a certain type of white blood cell (eosinophilia); abnormal muscle breakdown which may cause kidney problems; muscle pain; muscle stiffness; urine incontinence; difficulty in passing urine; withdrawal symptoms in newborn babies in case of exposure during pregnancy; prolonged and/or painful erection; difficulty controlling body temperature or overheating; chest pain; swelling of hands, ankles or feet; in blood tests – increased or fluctuating sugar level, increased glycosylated hemoglobin levels; inability to resist impulses or temptations to perform acts that could be harmful to you or others (such as a strong impulse to gamble excessively despite serious personal or family consequences; altered or increased sexual interest and behavior of significant concern to you or to others, for example, an increased sexual drive; excessive and uncontrollable shopping, binge eating [eating large amounts of food in a short time period] or compulsive eating [eating more food than normal and more than is needed to satisfy your hunger], a tendency to wander).

Additional side effects in children and adolescents:
The side effects observed in adolescents aged 13 years and older were similar in frequency and type to those observed in adults, except that sleepiness, involuntary twitching or movements, restlessness and tiredness were very common (more than 1 in 10 patients), upper abdominal pain, dry mouth, increased heart rate, weight gain, increased appetite, muscle twitching, involuntary movements of the limbs and dizziness (especially upon transition from lying or sitting to standing position) were common (more than 1 in 100 patients).

The following side effects were observed in children (ages 6-17) treated with aripiprazole:

Very common side effects (side effects occurring in more than one in ten users):
Sleepiness, tiredness and vomiting.

Common side effects (side effects occurring in 1-10 in 100 users):
Drowsiness, tremor, fever, excessive salivation, decreased appetite, involuntary twitching and movements, coma.

Uncommon side effects (side effects occurring in 1-10 in 1,000 users):
Blurred vision; nausea and vomiting, diarrhea, upper abdominal pain, constipation, dry mouth; nervousness; thirst, respiratory tract inflammation; weight gain; increased appetite, decreased appetite; muscle pain or stiffness; headache, restlessness, dizziness, muscle spasms, involuntary movements, increased need for sleep; menstrual pains; runny nose; skin rash.

In elderly patients with dementia, more fatalities have been reported during treatment with the medicine. In addition, cases of stroke or transient ischemic attack ("mini" stroke) have been reported.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store Aripiprazole Sandoz?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) which is stated on the package.
The expiry date refers to the last day of that month.

Storage conditions:
Do not store above 30˚C.

6. Additional information

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

Aripiprazole Sandoz 5:
Lactose monohydrate; maize starch; microcrystalline cellulose; magnesium stearate; hydroxypropyl cellulose; Indigo Carmine (E132) aluminium lake.

Aripiprazole Sandoz 10:
Lactose monohydrate; maize starch; microcrystalline cellulose; magnesium stearate; hydroxypropyl cellulose; iron oxide red (E172).

Aripiprazole Sandoz 15:
Lactose monohydrate; maize starch; microcrystalline cellulose; magnesium stearate; hydroxypropyl cellulose; iron oxide yellow (E172).

Aripiprazole Sandoz 30:
Lactose monohydrate; maize starch; microcrystalline cellulose; magnesium stearate; hydroxypropyl cellulose; iron oxide red (E172).

What the medicine looks like and contents of the pack:

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.

Registration holder and importer: Novartis Israel Ltd., P.O.Box 7126, Tel Aviv.

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

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