Patient leaflet in accordance with Pharmacist's Regulations (Preparations) 1986

This medicine is dispensed with a doctor's prescription only.

Abilify Maintena® 300 mg Abilify Maintena® 400 mg

Powder And Solvent for Prolonged-Release Suspension for Injection

Active ingredient

Each pre-filled syringe of **ABILIFY MAINTENA 300 MG** contains
aripiprazole 300 mg (as monohydrate)

After reconstitution each 1 mL of suspension contains 200 mg aripiprazole.

Each pre-filled syringe of **ABILIFY MAINTENA 400 MG** contains
aripiprazole 400 mg (as monohydrate)

After reconstitution each 1 mL of suspension contains 200 mg aripiprazole.

Inactive ingredients and allergens in this medicine: see section 2 under '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 illness is similar to yours.

1. What is this medicine intended for?

For maintenance treatment of schizophrenia in adult patients stabilized with aripiprazole tablets.
Therapeutic group: antipsychotics

2. Before using this medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient or any of the other ingredients of this medicine (see the list of inactive ingredients in section 6).

Special warnings about using this medicine

Talk to your doctor or nurse before you are given the medicine

Suicidal thoughts and behaviours have been reported during treatment with this medicine. Tell your doctor immediately if you are having thoughts about hurting yourself before or after receiving Abilify Maintena.

Before using Abilify Maintena, tell your doctor if you suffer from:

- an acutely agitated state or a severely psychotic state
- heart problems or have a history of stroke, especially if you know that you have other risks factors for stroke
- high blood sugar (characterised by symptoms such as excessive thirst, passing of large amounts of urine, increase in appetite and feeling weak) or family history of diabetes
- fits (seizures) your doctor may want to monitor you more closely
- involuntary, irregular muscle movements, especially in the face
- a combination of fever, sweating, rapid breathing, muscle stiffness and drowsiness or sleepiness (may be signs of neuroleptic malignant syndrome)
- dementia (loss of memory and other mental abilities) especially if you are elderly
- cardiovascular diseases (diseases of the heart and circulation), or family history of cardiovascular disease, stroke or "mini" stroke, abnormal blood pressure
- irregular heartbeat or if someone else in your family has a history of irregular heartbeat (including so called "QT prolongation" seen with ECG monitoring).
- blood clots, or family history of blood clots, as antipsychotics have been associated with formation of blood clots
- any difficulty in swallowing
- past experience with excessive gambling
- severe liver problems

If you notice you are gaining weight, develop unusual movements, experience sleepiness that interferes with normal daily activities, any difficulty in swallowing or have allergic symptoms, talk to your doctor immediately.

Tell your doctor if you or your family or 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 money, an abnormally high sex drive or an increase in compulsive sexual thoughts.
Your doctor may decide to adjust your dose or stop the treatment.

The medicine 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 an elderly patient or have some debility.

Children and adolescents
Do not use this medicine in children and adolescents under 18 years of age. It is not known if this treatment is safe and effective in children and adolescents.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are using:

Blood pressure-lowering medicines. Abilify Maintena may increase the effect of these medicines. Be sure to tell your doctor if you take a medicine to control your blood pressure.

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

- medicines to correct heart rhythm (such as quinidine, amiodarone, flecainide)
- antidepressants and herbal remedy used to treat depression and anxiety (such as fluoxetine, paroxetine, escitalopram, St. John's Wort)
- antifungal medicines (such as itraconazole)
- ketoconazole (used to treat Cushing's syndrome when the body produces an excess of cortisol)
- certain medicines to treat HIV infection (such as efavirenz, nevirapine, and protease inhibitors e.g. indinavir, ritonavir)
- anticonvulsants used to treat epilepsy (such as carbamazepine, phenytoin, phenobarbital)
- certain antibiotics used to treat tuberculosis (rifabutin, rifampicin)
- medicines that are known to prolong QT interval.

These medicines may increase the risk of side effects or reduce the effect of Abilify Maintena; if you get any unusual symptoms taking any of these medicines together with Abilify Maintena, you should contact your doctor.

Medicines that increase the level of serotonin are typically used in conditions including depression, generalised anxiety disorder, obsessive-compulsive disorder (OCD) and social phobia as well as migraine and pain:

- triptans, tramadol and tryptophan used for conditions including depression, generalised anxiety disorder, obsessive compulsive disorder (OCD) and social phobia as well as migraine and pain
- SSRI/SNRIs (such as paroxetine and fluoxetine) used for depression, OCD, panic and anxiety
- other antidepressants (such as venlafaxine and tryptophan) used in major depression
- Tricyclic antidepressants (such as clomipramine and amitriptyline) for depressive illness.
- (Hypericum perforatum (St John's Wort) - a herbal remedy for depression
- painkillers (such as tramadol and pethidine) used for pain relief
- triptans (such as sumatriptan and zolmitripitan) used for treating migraine

These medicines may increase the risk of side effects; if you get any unusual symptoms taking any of these medicines together with Abilify Maintena, you should contact your doctor.

Using this medicine and alcohol consumption
Alcohol use should be avoided.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before receiving this medicine.
Do not use Abilify Maintena if you are pregnant unless you have discussed this with your doctor. Please inform your doctor immediately if you are pregnant, think you may be pregnant, or if you are planning to become pregnant.

The following symptoms may occur in newborn babies of mothers that have received Abilify Maintena in the last three months of their pregnancy (in the last trimester):
shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding.

If your baby develops any of these symptoms, you need to contact your doctor.

If you are receiving Abilify Maintena, your doctor will discuss with you whether you should breastfeed considering the benefit of your therapy to you and the benefit of breastfeeding to your baby. Do not breastfeed during the period of treatment with Abilify Maintena. Consult your doctor about the best way to feed your baby if you are receiving Abilify Maintena.

Driving and using machines
Dizziness and vision problems may occur during treatment with this medicine (see also in section 4). This should be considered in cases where full alertness is required, e.g., when driving a car or handling machines.

Important information about some of this medicine's ingredients
Abilify Maintena contains sodium
Abilify Maintena contains less than 1 mmol sodium (23 mg) per dose. This means that the medicine is essentially 'sodium-free'.

3. How to take this medicine?

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.
This medicine comes as a pre-filled syringe. Your doctor will decide on the dose of Abilify Maintena that is right for you.

The recommended starting dose is 400 mg unless your doctor decided to give you a lower starting or follow-up dose. The interval between two injections should not be shorter than 26 days. Treatment with aripiprazole by mouth is continued for 14 days after the first injection. After that, treatment is continued with injections of Abilify Maintena unless your doctor tells you otherwise.

Your doctor will give you a single injection each month into the buttock or shoulder muscle. You may feel a little pain during the injection.
Your doctor will alternate the injections between your right and left side. The injections should not be given intravenously.

Do not exceed the recommended dose.

If you have accidentally been given more Abilify Maintena than you should
This medicine will be given to you under medical supervision; it is therefore unlikely that you will be given more than the recommended dose. If you are being treated by more than one doctor, be sure to tell them that you are receiving Abilify Maintena.

Patients who have been given too much of this medicine have experienced the following symptoms:
- rapid heartbeat, agitation/aggressiveness, problems with speech.
- unusual movements (especially of the face or tongue) and reduced level of consciousness.

Other symptoms may include:
- acute confusion, seizures (epilepsy), coma, a combination of fever, rapid breathing, sweating.
- muscle stiffness, drowsiness or sleepiness, slow breathing, choking, high or low blood pressure, abnormal rhythms of the heart.

Contact your doctor or hospital immediately if you experience any of the above.

If you miss an injection
It is important not to miss your scheduled dose. You should be given an injection every month but not before the 26 days has passed from the last injection. If you miss an injection, you should contact your doctor to arrange your next injection as soon as you can.

Adhere to the treatment as recommended by your doctor

I**f you stop receiving Abilify Maintena**
Even if there is an improvement in your health, do not stop treatment with this medicine without consulting your doctor. It is important that you carry on receiving the medicine for as long as your doctor has told you to.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor.

4. Side effects

As with any medicine, using Abilify Maintena may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects
Contact your doctor immediately if you have any of the following serious side effects:

- a combination of any of these symptoms: excessive sleepiness, dizziness, confusion, disorientation, difficulty talking, difficulty walking, muscle stiffness or shaking, fever, weakness, irritability, aggression, anxiety, increase in blood pressure, or seizures that can lead to unconsciousness.
- unusual movement mainly of the face or tongue, since your doctor may want to lower your dose.
- if you have symptoms such as swelling, pain, and redness in the leg, because this may mean you have a blood clot, which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.
- a combination of fever, rapid breathing, sweating, muscle stiffness and drowsiness or sleepiness since this may be a sign of a condition called neuroleptic malignant syndrome (NMS).
- Increased thirst, frequent urination, excessive hunger, unusual tiredness or weakness, nausea, confusion, or fruity-smelling breath, since these may be signs of diabetes.
- suicidal thoughts, behaviours or thoughts and feelings about hurting yourself.

The following side effects may also occur after receiving Abilify Maintena. Tell your doctor or nurse if you are affected by any of these side effects:

Common side effects - affect 1–10 in 100 users:

- weight gain
- diabetes mellitus
- weight loss
- feeling restless
- feeling anxious
- unable to keep still, difficulty sitting still
- difficulty sleeping (insomnia)
- jerky resistance to passive movement as muscles tense and relax, abnormally increased muscle tone, slow body movements
- akathisia (an uncomfortable feeling of inner restlessness and a compelling need to move constantly)
- shaking
- uncontrollable twitching, jerking or writhing movements
- changes in your level of alertness, drowsiness
- sleepiness
- dizziness
- headache
- dry mouth
- muscle stiffness
- inability to have or maintain an erection during sexual intercourse
- pain at the injection site, hardening of the skin at the injection site
- weakness, loss of strength or extreme tiredness
- blood test results might show high levels of creatine phosphokinase in your blood (enzyme important for muscle function)

Uncommon side effects - affect up to 1 in 100 users:

- low level of a specific type of white blood cells (neutropenia), low haemoglobin or red blood cell count, low level of blood platelets
- allergic reactions (hypersensitivity)
- decreased or increased blood levels of the hormone prolactin
- high blood sugar
- increased blood fats such as high cholesterol, high triglycerides and also low level of cholesterol and low level of triglycerides
- increased levels of insulin, a hormone regulating blood sugar levels
- decreased or increased appetite
- thoughts about suicide
- mental disorder characterized by defective or lost contact with reality
- hallucination
- delusions
- increased sexual interest

- panic reaction
- depression
- emotional lability (mood swings)
- state of indifference with lack of emotion, feelings of emotional and mental discomfort
- sleep disorder
- grinding of teeth or clenching of the jaw
- reduced sexual interest (libido is decreased)
- altered mood
- muscle problems
- muscle movements that you cannot control such as grimacing, lip-smacking and tongue movements. They usually affect the face and mouth first but can affect other parts of the body. These could be signs of a condition called “tardive dyskinesia”.
- parkinsonism - medical condition with many various symptoms which include decreased or slow movements, slowness of thought, jerks when bending the limbs (cogwheel rigidity), shuffling, hurried steps, shaking, little or no facial expression, muscle stiffness, drooling
- movement problems
- extreme restlessness and restless legs
- distortion of the senses of taste and smell
- fixation of the eyeballs in one position
- blurred vision
- eye pain
- double vision
- eye sensitivity to light
- abnormal heartbeat, slow or fast heart rate, abnormal electrical conduction of the heart, abnormal reading (ECG) of the heart
- high blood pressure
- dizziness when getting up from a lying or sitting position due to a drop in blood pressure
- cough
- hiccups
- gastroesophageal reflux disease. Excess amount of gastric juice flowing back (refluxes) into the esophagus (gullet or the tube that goes from mouth to stomach through which food passes), causing heartburn and possibly damaging the esophagus
- heartburn
- vomiting
- diarrhoea
- nausea (feeling sick)
- stomach-ache
- stomach discomfort
- constipation
- frequent bowel movement
- drooling, more saliva in mouth than normal
- abnormal hair loss
- acne, skin condition of the face where the nose and cheeks are unusually red, eczema, skin hardening
- muscle rigidity, muscle spasms, muscle twitching, muscle tightness, muscle pain (myalgia), pain in extremity
- joint pain (arthralgia), back pain, decreased range of motion of joints, stiff neck, limited opening of mouth
- kidney stones, sugar (glucose) in urine
- spontaneous flow of milk from the breasts (galactorrhoea)
- enlargement of breast in men, breast tenderness, vaginal dryness
- fever
- loss of strength (becoming weak)
- gait disturbance
- chest discomfort
- injection site reactions such as redness, swelling discomfort and injection site itching
- thirst
- sluggishness
- liver function tests may show abnormal results
- during tests your doctor may find
  - increased liver enzymes levels
  - increased alanine aminotransferase levels
  - increased gamma-glutamyl transferase levels
  - increased bilirubin levels in your blood
  - increased aspartate aminotransferase levels
  - increased or decreased blood glucose levels
  - increased glycosylated haemoglobin levels
  - decreased cholesterol levels in your blood

- decreased triglyceride levels in your blood
- increased waist circumference

The following side effects have been reported since the marketing of medicines containing the same active substance that are taken by mouth, but their frequency is not known (frequency cannot be estimated from the available data):

- low levels of white blood cells
- allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching, hives), rash
- unusual heartbeat, sudden unexplained death, heart attack
- diabetic ketoacidosis (ketones in the blood and urine) or coma
- loss of appetite (anorexia), difficulty in swallowing
- low sodium levels in the blood
- suicide attempts and suicides
- inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
  - strong impulse to gamble excessively despite serious personal or family consequences
  - altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive
  - uncontrollable excessive 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 away

Tell your doctor if you experience any of these behaviours; he/she will discuss ways of managing or reducing the symptoms.

- nervousness
- aggression
- a condition called neuroleptic malignant syndrome (a syndrome with symptoms such as fever, muscle stiffness, rapid breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate)
- seizures (fits)
- serotonin syndrome (a reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles)
- speech disorders
- heart problems including torsades de pointes, stopping of the heart, irregularities in heart rhythm that may be due to abnormal nerve impulses in the heart, abnormal readings during heart examination (ECG) called QT prolongation
- fainting
- symptoms related to blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing
- spasm of the muscles around the voice box
- accidental inhalation of food with risk of pneumonia (lung infection)
- inflammation of the pancreas
- difficulty swallowing
- liver failure
- jaundice (yellowing of the skin and white part of eyes)
- inflammation of the liver
- rash
- skin sensitivity to light
- 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).
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis)
- difficulty in passing urine
- involuntary loss of urine (incontinence)
- drug withdrawal symptoms in newborn infants
- prolonged and/or painful erection
- difficulty controlling core body temperature or overheating
- chest pain
- swelling of hands, ankles or feet
- during tests your doctor may find

- higher levels of alkaline phosphatase
- fluctuating results during tests to measure glucose levels in your blood

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 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

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 and the pre-filled syringe. The expiry date refers to the last day of that month.

Storage conditions:
Do not freeze.
Keep the pre-filled syringe in the outer carton in order to protect from light.
After preparation, if the injection is not performed immediately, the syringe can be kept below 25 °C for up to 2 hours.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Powder:
Mannitol, carmellose sodium, sodium dihydrogen phosphate monohydrate, sodium hydroxide
Solvent:
Water for injections

What the medicine looks like and contents of the pack:
Pre-filled syringe with prolonged-release medicine; contains a white to off-white powder in the front chamber and a clear, colourless liquid in the rear chamber.

Your doctor will make it into a suspension that will be given as an injection.

- Single pack
- Bundle pack of 3 single packs

Not all pack sizes may be marketed.

Each single pack contains one pre-filled syringe, three hypodermic safety needles: one 25 mm (1 inch) 23 gauge, one 38 mm (1.5 inch) 22 gauge and one 51 mm (2 inch) 21 gauge.

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Revised in July 2025.

Registration number of the medicine in the Ministry of Health National Drug Registry:

153-68-34089
153-69-34094