

Package leaflet: Information for the user

Abilify Maintena 720 mg prolonged-release suspension for injection in pre-filled syringe Abilify Maintena 960 mg prolonged-release suspension for injection in pre-filled syringe aripiprazole

Read all of this leaflet carefully before you receive this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Abilify Maintena is and what it is used for
2. What you need to know before you are given Abilify Maintena
3. How Abilify Maintena is given
4. Possible side effects
5. How to store Abilify Maintena
6. Contents of the pack and other information

1. What Abilify Maintena is and what it is used for

Abilify Maintena contains the active substance aripiprazole in a pre-filled syringe.

Aripiprazole belongs to a group of medicines called antipsychotics. Abilify Maintena is used to treat schizophrenia - a disease with 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.

Abilify Maintena is intended for adult patients with schizophrenia who are sufficiently stabilised during treatment with aripiprazole.

If you have responded well to treatment with aripiprazole taken by mouth or the medicine Abilify Maintena, your doctor may start treatment with Abilify Maintena. It can help alleviate the symptoms of your disease and reduce the risk of your symptoms coming back.

2. What you need to know before you are given Abilify Maintena

Do not use Abilify Maintena

- if you are allergic to aripiprazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or nurse before you are given Abilify Maintena.

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

Before treatment with this medicine, tell your doctor if you suffer from:

- an acutely agitated state or a severely psychotic state
- cardiovascular diseases (diseases of the heart and circulation), family history of cardiovascular disease, stroke or "mini" stroke, abnormal blood pressure

- heart problems or have a history of stroke, especially if you know that you have other risks factors for stroke
- blood clots, or family history of blood clots, as antipsychotics have been associated with formation of blood clots
- irregular heartbeat or if someone else in your family has a history of irregular heartbeat (including so called QT prolongation seen with ECG monitoring)
- involuntary, irregular muscle movements, especially in the face (tardive dyskinesia)
- experience a combination of fever, sweating, faster breathing, muscle stiffness and drowsiness or sleepiness (may be signs of neuroleptic malignant syndrome)
- fits (seizures) since your doctor may want to monitor you more closely
- dementia (loss of memory and other mental abilities) especially if you are elderly
- 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
- have any difficulty in swallowing
- past experience with excessive gambling.

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, please talk to your doctor immediately.

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.

Your doctor may need to adjust or stop your dose.

This 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 it is safe and effective in these patients.

Other medicines and Abilify Maintena

Tell your doctor if you are taking, have recently taken or might take any other medicines.

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

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 the following to your doctor:

- medicines to correct heart rhythm (such as quinidine, amiodarone, flecainide, diltiazem)
- antidepressants or 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, primidone)
- certain antibiotics used to treat tuberculosis (rifabutin, rifampicin)
- medicines that are known to prolong QT prolongation.

These medicines may increase the risk of side effects or reduce the effect of Abilify Maintena; if you get any unusual symptom taking any of these medicines together with Abilify Maintena, you should see 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, OCD and social phobia as well as migraine and pain
- selective serotonin reuptake inhibitor/serotonin noradrenaline reuptake inhibitor (SSRI/SNRI s) such as paroxetine and fluoxetine used for depression, OCD, panic, and anxiety
- other anti-depressants (such as venlafaxine and tryptophan) used in major depression
- tricyclic's (such as clomipramine and amitriptyline) used for depressive illness
- St John's Wort (*Hypericum perforatum*) used as an herbal remedy for mild depression
- painkillers (such as tramadol and pethidine) used for pain relief
- triptans (such as sumatriptan and zolmitriptan) used for treating migraine.

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

Abilify Maintena with alcohol

Alcohol should be avoided.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before receiving this medicine.

You should not be given Abilify Maintena if you are pregnant unless you have discussed this with your doctor. Be sure to tell 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 new-born babies, of mothers that receive this medicine in the last three months of their pregnancy (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 breast-feed considering the benefit to you of your therapy and the benefit to your baby of breast-feeding. You should not do both. Talk to your doctor about the best way to feed your baby if you are receiving this medicine.

Driving and using machines

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

Abilify Maintena contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How Abilify Maintena is given

Abilify Maintena comes as a suspension in a pre-filled syringe which your doctor or nurse will administer.

Your doctor will decide on the dose that is right for you. The recommended starting dose is 960 mg injected once every 2 months (56 days after the previous injection) unless your doctor decided to give you a lower starting or follow up dose (720 mg) injected once every 2 months (56 days after the previous injection).

There are three ways to start Abilify Maintena 960 mg, your doctor will decide which way is right for you.

- If you received Abilify Maintena 400 mg 1 or more months before your doctor started treatment with Abilify Maintena 960 mg, your next dose may be replaced with one injection of Abilify Maintena 960 mg.
- If you are given one injection of Abilify Maintena 960 mg on your first day without administration of Abilify Maintena 400 mg 1 month before, the treatment with aripiprazole by mouth is continued for 14 days after the first injection.
- If you are given two injections (one of Abilify Maintena 960 mg and one of Abilify Maintena 400 mg) on your first day, you will also take one tablet of aripiprazole by mouth at this visit. Your doctor will give the injections in two different sites.

After that, treatment is given with injections of Abilify Maintena 960 mg or 720 mg unless your doctor tells you otherwise.

Your doctor will give it to you as a single injection into the gluteal muscle (buttock) once every two months. You may feel a little pain during the injection. Your doctor will alternate the injections between your right and left side. The injections will not be given intravenously.

If you are 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 too much. If you see more than one doctor, be sure to tell them that you are receiving this medicine.

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, faster breathing, sweating,
- muscle stiffness, and drowsiness or sleepiness, slower 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 of Abilify Maintena

It is important not to miss your scheduled dose. You should be given an injection once every 2 months. If you miss an injection, you should contact your doctor to arrange your next injection as soon as you can.

If you stop receiving Abilify Maintena

Do not stop your treatment just because you feel better. It is important that you carry on receiving this medicine for as long as your doctor has told you to.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell 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, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness since this may be a sign of a condition called neuroleptic malignant syndrome (NMS).
- thirstiness more than usual, need to urinate more than usual, feel very hungry, feel weak or tired, feel sick, feel confused or your breath smells fruity, since this may be a sign of diabetes.
- suicidal thoughts, behaviours or thoughts and feelings about hurting yourself.

The side effects listed below may also occur after receiving Abilify Maintena

Talk to your doctor or nurse if you are affected by any of these side effects:

Common side effects (may affect up to 1 in 10 people):

- diabetes mellitus
- 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 movement
- akathisia (an uncomfortable feeling of inner restlessness and a compelling need to move constantly)
- shaking or trembling
- 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
- during blood tests your doctor may find higher amounts of creatine phosphokinase in your blood (enzyme important for muscle function)
- weight gain
- weight loss

Uncommon side effects (may affect up to 1 in 100 people):

- 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 (e.g., swelling in the mouth, tongue, face and throat, itching, hives)
- increased blood levels of the hormone prolactin
- high blood sugar
- increased blood fats such as high cholesterol and high triglycerides
- increased levels of insulin, a hormone regulating blood sugar levels
- decreased or increased appetite
- thoughts about suicide
- mental disorder characterised by defective or lost contact with reality
- hallucination (e.g. seeing and hearing things that are not real)
- delusion (e.g. believing things that are not true)
- increased sexual interest (may lead to behaviour of significant concern to you or to others)
- panic reaction
- depression
- affect lability
- 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
- fixation of the eyeballs in one position
- blurred vision
- eye pain
- double vision
- eye sensitivity to light
- distortion of the senses of taste and smell
- abnormal heartbeat, slow or fast heart rate
- high blood pressure
- dizziness when getting up from a lying or sitting position due to a drop in blood pressure
- cough
- hiccups
- gastrooesophageal reflux disease. Excess amount of gastric juice flowing back (refluxes) into the oesophagus (gullet or the tube that goes from mouth to stomach through which food passes), causing heartburn and possibly damaging the oesophagus
- heartburn
- vomiting
- diarrhoea
- 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
- gait disturbance
- chest discomfort
- injection site reactions such as redness, swelling, discomfort and injection site itching
- thirst
- sluggishness
- during tests your doctor may find
 - higher or lower amounts of blood glucose
 - higher amounts of glycosylated haemoglobin
 - a higher waist circumference
 - lower amounts of cholesterol in your blood
 - lower amounts of triglycerides in your blood
 - lower amounts of white blood cells and neutrophils in your blood
 - higher amounts of liver enzymes
 - lower amounts of the hormone prolactin in your blood
 - abnormal reading (ECG) of the heart (e.g. T wave amplitude decreased or inverted)
 - higher amounts of alanine aminotransferase
 - higher amounts of gamma-glutamyl transferase
 - higher amounts of bilirubin in your blood
 - higher amounts of aspartate aminotransferase
- liver function tests may show abnormal results

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

- low levels of white blood cells
 - decreased appetite
 - low sodium level in the blood
 - suicide and suicide attempt
 - 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
 - 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
 - neuroleptic malignant syndrome (a syndrome with symptoms such as fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate)
 - seizure (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
 - diabetic ketoacidosis (ketones in the blood and urine) or coma

- fainting
- heart problems including stopping of the heart, torsades de pointes, irregularities in heart rhythm that may be due to abnormal nerve impulses in the heart
- 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 in your throat that can lead to a feeling as though a large object is stuck in your throat
- spasm of the muscles around the voice box
- accidental inhalation of food with risk of pneumonia (lung infection)
- inflammation of the pancreas
- difficulty in 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)
- withdrawal symptoms in new-born infant
- prolonged and/or painful erection
- sudden unexplained death
- difficulty controlling core body temperature or overheating
- chest pain
- swelling of hands, ankles or feet
- during tests your doctor may find
 - fluctuating results during tests to measure glucose in your blood
 - QT prolongation (an abnormal readings during heart examination (ECG))
 - higher amounts of alkaline phosphatase in your blood

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Abilify Maintena

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the pre-filled syringe. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Abilify Maintena contains

- The active substance is aripiprazole.

Abilify Maintena 720 mg prolonged-release suspension for injection in pre-filled syringe

Each pre-filled syringe contains 720 mg aripiprazole.

Abilify Maintena 960 mg prolonged-release suspension for injection in pre-filled syringe

Each pre-filled syringe contains 960 mg aripiprazole.

- The other ingredients are:
Carmellose sodium, macrogol, povidone (E1201), sodium chloride, sodium dihydrogen phosphate monohydrate (E339), sodium hydroxide (E524), water for injections.(see section 2, Abilify Maintena contains sodium)

What Abilify Maintena looks like and contents of the pack

Abilify Maintena is a prolonged-release suspension for injection in a pre-filled syringe.

Abilify Maintena is a white to off-white prolonged-release suspension for injection in a pre-filled syringe.

Pack size

Each 720 mg pack contains one pre-filled syringe, and two sterile safety needles: one 38 mm (1.5 inch) 22 gauge and one 51 mm (2 inch) 21 gauge.

Each 960 mg pack contains one pre-filled syringe and two sterile safety needles: one 38 mm (1.5 inch) 22 gauge and one 51 mm (2 inch) 21 gauge.

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This leaflet was last revised in 02/2024