Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist 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 out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not freeze.
- The reconstituted suspension should be used immediately but may be stored below 25°C for up to 4 hours in the vial. Do not store the reconstituted suspension in the syringe.
- If the medicines become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Abilify Maintena® contains

The active substance is aripiprazole.

Each vial contains 400 mg aripiprazole.

After reconstitution each mL of suspension contains 200 mg aripiprazole.

The other ingredients are

Powder:

Carmellose sodium, mannitol (E421), sodium dihydrogen phosphate monohydrate (E339), sodium hydroxide (E524).

Solvent:

Water for injections.

What Abilify Maintena® looks like and contents of the pack

Abilify Maintena® is a powder and solvent for prolonged-release suspension for injection.

Abilify Maintena® comes as a white to off-white powder in a clear glass vial. Your doctor or nurse will make it into a suspension that will be given as an injection using the vial of solvent for Abilify Maintena® that comes as a clear solution in a clear glass vial.

Single pack

Each single pack containing one vial of powder, 2 mL vial of solvent, one 3 mL luer lock syringe with pre-attached 38 mm (1.5 inch) 21 gauge, hypodermic safety needle with needle protection device, one 3 mL disposable syringe with luer lock tip, one vial adapter and 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.

Manufactured by H. Lundbeck A/S, Ottiliavej 9, 2500 Valby, Denmark.

Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU.

Revision date: 01.08.2025

PL 16378/1224 **POM**

Leaflet reference: ABI/PA

Abilify Maintena® is a registered trademark of Otsuka Pharmaceutical Co., LTD.

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Beachcourse,
Tel: 020 8896 9054 for help.
Ref. number: 1224/V3

Package Leaflet: Information for the User

Abilify Maintena® 400 mg
powder and solvent for prolonged-release suspension for injection

(aripiprazole)

Your medicine is known by the above name, but will be referred to as Abilify Maintena® throughout this leaflet.

This medicine is also available in another strength.

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 vial. 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 taken by mouth.

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 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) since your doctor may want to monitor you more closely
- involuntary, irregular muscle movements, especially in the face
- experience a combination of fever, sweating, faster 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), family history of cardiovascular disease, stroke or "mini" stroke, abnormal blood pressure
- irregular heart beat or if someone else in your family has a history of irregular heart beat (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
- have 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, 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)
- antidepressants or herbal remedy used to treat depression and anxiety (such as fluoxetine, paroxetine, 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 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, obsessive compulsive disorder (OCD) and social phobia as well as migraine and pain
- SSRI 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 a herbal remedy for mild 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 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 have received Abilify Maintena® 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 Abilify Maintena®.

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 a car 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 powder which your doctor or nurse will make into a suspension.

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.

There are two ways to start Abilify Maintena®, your doctor will decide which way is right for you.

- If you are given one injection of Abilify Maintena® on your first day the treatment with aripiprazole by mouth is continued for 14 days after the first injection.
- If you are given two injections of Abilify Maintena® on your first day, you will also take one tablet of aripiprazole by mouth at this visit.

After that, treatment is given with injections of Abilify Maintena® unless your doctor tells you otherwise.

Your doctor will give it to you as a single injection into the gluteal or deltoid muscle (buttock or shoulder) every month. 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 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, 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 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.

If you stop receiving Abilify Maintena®

Do not stop your treatment just because you feel better. It is important that you carry on receiving Abilify Maintena® 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):

- 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 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)

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 (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 characterised by defective or lost contact with reality
- hallucination

- delusion
- increased sexual interest
- 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, lipsmacking 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
- 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, mucle 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
- liver function tests may show abnormal results
- during tests your doctor may find
    - higher amounts of liver enzymes
    - higher amounts of alanine aminotransferase
    - higher amounts of gamma-glutamyl transferase
    - higher amounts of bilirubin in your blood
    - higher amounts of aspartate aminotransferase
    - higher or lower amounts of blood glucose
    - higher amounts of glycosylated haemoglobin
    - lower amounts of cholesterol in your blood
    - lower amounts of triglycerides in your blood
    - a higher 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 the frequency for them to occur 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 level in the blood
- suicide attempt and suicide
- 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
- 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
- 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) 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 flulike 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 new-born infant
- 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 amounts alkaline phosphatase
    - fluctuating results during tests to measure glucose in your blood

The following information is intended for healthcare professionals only:

INSTRUCTIONS FOR HEALTH CARE PROFESSIONALS

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

Abilify Maintena® 400 mg
powder and solvent for prolonged-release suspension for injection

(aripiprazole)

Step 1: Preparation prior to reconstitution of the powder

Lay out and confirm that components listed below are provided:

- Abilify Maintena® package leaflet and instructions for healthcare professionals.
- Vial of powder.
- 2 ml vial of solvent.

Important: the solvent vial contains an overfill.

- One 3 ml luer lock syringe with pre-attached 38 mm (1.5 inch) 21 gauge hypodermic safety needle with needle protection device.
- One 3 ml disposable syringe with luer lock tip.
- One vial adapter.
- One 25 mm (1 inch) 23 gauge hypodermic safety needle with needle protection device.
- One 38 mm (1.5 inch) 22 gauge hypodermic safety needle with needle protection device.
- One 51 mm (2 inch) 21 gauge hypodermic safety needle with needle protection device.
- Syringe and needle instructions.

Step 2: Reconstitution of the powder

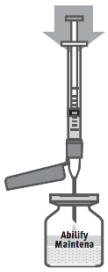
a) Remove the solvent and powder vial caps and wipe the tops with a sterile alcohol swab.

b) Using the syringe with pre-attached needle, withdraw the pre-determined solvent volume from the vial of the solvent into the syringe.

400 mg vial:

Add 1.9 mL solvent to reconstitute the powder.

A small amount of residual solvent will remain in the vial following withdrawal. Any excess should be discarded.

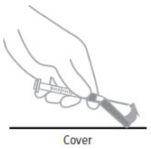


c) Slowly inject the solvent into the vial containing the powder.

d) Withdraw air to equalise the pressure in the vial by pulling back slightly on the plunger.

e) Subsequently, remove the needle from the vial.

Engage the needle safety device by using the onehanded technique.



Gently press the sheath against a flat surface until the needle is firmly engaged in the needle protection sheath.
Visually confirm that the needle is fully engaged into the needle protection sheath, and discard.

f) <u>Shake the vial vigorously for at least 30 seconds until the suspension appears uniform.</u>

g) Visually inspect the reconstituted suspension for particulate matter and discolouration prior to administration. The reconstituted medicine is a white to off-white, fluid suspension. Do not use if reconstituted suspension contains particulate matter or any discolouration.

h) If the injection is not performed immediately after reconstitution, keep the vial below 25 °C for up to 4 hours and shake it vigorously for at least 60 seconds to re-suspend prior to injection.

I) Do not store the reconstituted suspension in the syringe.

Step 3: Preparation prior to injection

a) Remove the cover, but not the adapter from the package.

b) Using the vial adapter package to handle the vial adapter, attach the pre-packaged luer lock syringe to the vial adapter.

c) Use the luer lock syringe to remove the vial adapter from the package and discard the vial adapter package. <u>Do not touch the spike tip of the adapter at any time.</u>

d) Determine the recommended volume for injection.

Abilify Maintena® 400 mg vial

Dose	Volume to Inject
400 mg	2.0 mL
300 mg	1.5 mL
200 mg	1.0 mL
160 mg	0.8 mL

e) Wipe the top of the vial of the reconstituted suspension with a sterile alcohol swab.

f) Place and hold the vial of the reconstituted suspension on a hard surface. Attach the adapter-syringe assembly to the vial by holding the outside of the adapter and pushing the adapter's spike firmly through the rubber stopper, until the adapter snaps in place.

g) Slowly withdraw the recommended volume from the vial into the luer lock syringe to allow for injection.

<u>A small amount of excess product will remain in the vial.</u>

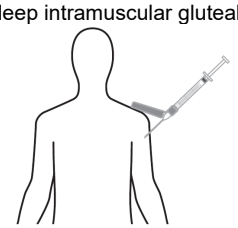
Step 4: Injection procedure

a) Detach the luer lock syringe containing the recommended volume of reconstituted Abilify Maintena® suspension from the vial.
b) Select one of the following hypodermic safety needles depending on the injection site and patient's weight and attach the needle to the luer lock syringe containing the suspension for injection. Ensure the needle is firmly seated on the needle protection device with a push and clockwise twist and then pull the needle cap straight away from the needle.

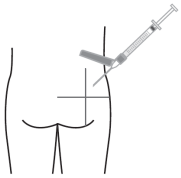
Body type	Injection site	Needle size
Non-obese	Deltoid Gluteal	25 mm (1 inch) 23 gauge 38 mm (1.5 inch) 22 gauge
Obese	Deltoid Gluteal	38 mm (1.5 inch) 22 gauge 51 mm (2 inch) 21 gauge

c) Slowly inject the recommended volume as a single intramuscular injection into the gluteal or deltoid muscle. Do not massage the injection site. Care must be taken to avoid inadvertent injection into the blood vessel. Do not inject into an area with signs of inflammation, skin damage, lumps and/or bruises.

For deep intramuscular gluteal or deltoid injection only.



deltoid



gluteal

Remember to rotate sites of injections between the two gluteal or deltoid muscles.
If initiating with the two injection start, inject into two different sites in two different muscles. DO NOT inject both injections concomitantly into the same deltoid or gluteal muscle.
For known CYP2D6 poor metabolisers administer in either two separate deltoid muscles or one deltoid and one gluteal muscle. DO NOT inject into two gluteal muscles.
Look for signs or symptoms of inadvertent intravenous administration.

Step 5: Procedures after injection

Engage the needle safety device as described in Step 2 e). Dispose of the vials, adapter, needles, and syringe appropriately after injection.
The powder and solvent vials are for single-use only.

PL 16378/1224

Revision date: 01.08.2025

Leaflet reference: ABI/ME/V3

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist 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 ARIPIPRAZOLE OTSUKA

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not freeze.
- The reconstituted suspension should be used immediately but may be stored below 25°C for up to 4 hours in the vial. Do not store the reconstituted suspension in the syringe.
- If the medicines become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Aripiprazole Otsuka contains

The active substance is aripiprazole.

Each vial contains 400 mg aripiprazole.

After reconstitution each mL of suspension contains 200 mg aripiprazole.

The other ingredients are

Powder:

Carmellose sodium, mannitol (E421), sodium dihydrogen phosphate monohydrate (E339), sodium hydroxide (E524).

Solvent:

Water for injections.

What Aripiprazole Otsuka looks like and contents of the pack

Aripiprazole Otsuka is a powder and solvent for prolonged-release suspension for injection.

Aripiprazole Otsuka comes as a white to off-white powder in a clear glass vial. Your doctor or nurse will make it into a suspension that will be given as an injection using the vial of solvent for Aripiprazole Otsuka that comes as a clear solution in a clear glass vial.

Single pack

Each single pack containing one vial of powder, 2 mL vial of solvent, one 3 mL luer lock syringe with pre-attached 38 mm (1.5 inch) 21 gauge, hypodermic safety needle with needle protection device, one 3 mL disposable syringe with luer lock tip, one vial adapter and 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.

Manufactured by H. Lundbeck A/S, Ottiliavej 9, 2500 Valby, Denmark.

Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU.

Revision date: 01.08.2025

PL 16378/1224 **POM**

Leaflet reference: ARI/PA

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Beachcourse,
Tel: 020 8896 9054 for help.
Ref. number: 1224/V3

Package Leaflet: Information for the User

Aripiprazole Otsuka 400 mg
powder and solvent for prolonged-release suspension for injection

Your medicine is known by the above name, but will be referred to as Aripiprazole Otsuka throughout this leaflet.

This medicine is also available in another strength.

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

1. WHAT ARIPIPRAZOLE OTSUKA IS AND WHAT IT IS USED FOR

Aripiprazole Otsuka contains the active substance aripiprazole in a vial. Aripiprazole belongs to a group of medicines called antipsychotics. Aripiprazole Otsuka 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.

Aripiprazole Otsuka is intended for adult patients with schizophrenia who are sufficiently stabilised during treatment with aripiprazole taken by mouth.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN ARIPIPRAZOLE OTSUKA

Do not use Aripiprazole Otsuka
- 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 Aripiprazole Otsuka.

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 Aripiprazole Otsuka.

Before treatment with Aripiprazole Otsuka, 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) since your doctor may want to monitor you more closely
- involuntary, irregular muscle movements, especially in the face
- experience a combination of fever, sweating, faster 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), family history of cardiovascular disease, stroke or "mini" stroke, abnormal blood pressure
- irregular heart beat or if someone else in your family has a history of irregular heart beat (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
- have 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, 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 Aripiprazole Otsuka

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

Blood pressure-lowering medicines: Aripiprazole Otsuka 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 Aripiprazole Otsuka with some medicines may mean the doctor will need to change your dose of Aripiprazole Otsuka 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)
- antidepressants or herbal remedy used to treat depression and anxiety (such as fluoxetine, paroxetine, 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 prolongation.

These medicines may increase the risk of side effects or reduce the effect of Aripiprazole Otsuka; if you get any unusual symptom taking any of these medicines together with Aripiprazole Otsuka, 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, obsessive compulsive disorder (OCD) and social phobia as well as migraine and pain
- SSRI 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 a herbal remedy for mild 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 symptom taking any of these medicines together with Aripiprazole Otsuka, you should see your doctor.

Aripiprazole Otsuka 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 Aripiprazole Otsuka 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 have received Aripiprazole Otsuka 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 Aripiprazole Otsuka, 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 Aripiprazole Otsuka.

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 a car or handling machines.

Aripiprazole Otsuka contains sodium

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

3. HOW ARIPIPRAZOLE OTSUKA IS GIVEN

Aripiprazole Otsuka comes as a powder which your doctor or nurse will make into a suspension.

Your doctor will decide on the dose of Aripiprazole Otsuka 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.

There are two ways to start Aripiprazole Otsuka, your doctor will decide which way is right for you.

- If you are given one injection of Aripiprazole Otsuka on your first day the treatment with aripiprazole by mouth is continued for 14 days after the first injection.
- If you are given two injections of Aripiprazole Otsuka on your first day, you will also take one tablet of aripiprazole by mouth at this visit.

After that, treatment is given with injections of Aripiprazole Otsuka unless your doctor tells you otherwise.

Your doctor will give it to you as a single injection into the gluteal or deltoid muscle (buttock or shoulder) every month. 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 Aripiprazole Otsuka 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 Aripiprazole Otsuka.

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 Aripiprazole Otsuka

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.

If you stop receiving Aripiprazole Otsuka

Do not stop your treatment just because you feel better. It is important that you carry on receiving Aripiprazole Otsuka 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 Aripiprazole Otsuka.

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):

- 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 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)

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 (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 characterised by defective or lost contact with reality
- hallucination
- delusion
- increased sexual interest
- 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, lipsmacking 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
- 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, mucle 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
- liver function tests may show abnormal results
- during tests your doctor may find
  - higher amounts of liver enzymes
  - higher amounts of alanine aminotransferase
  - higher amounts of gamma-glutamyl transferase
  - higher amounts of bilirubin in your blood
  - higher amounts of aspartate aminotransferase
  - higher or lower amounts of blood glucose
  - higher amounts of glycosylated haemoglobin
  - lower amounts of cholesterol in your blood
  - lower amounts of triglycerides in your blood
  - a higher 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 the frequency for them to occur 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 level in the blood
- suicide attempt and suicide
- 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
- 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
- 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) 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 flulike 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 new-born infant
- 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 amounts alkaline phosphatase
  - fluctuating results during tests to measure glucose in your blood

The following information is intended for healthcare professionals only:

INSTRUCTIONS FOR HEALTH CARE PROFESSIONALS

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

Aripiprazole Otsuka 400 mg
powder and solvent for prolonged-release suspension for injection

Step 1: Preparation prior to reconstitution of the powder

Lay out and confirm that components listed below are provided:

- Aripiprazole Otsuka package leaflet and instructions for healthcare professionals.
- Vial of powder.
- 2 ml vial of solvent.

Important: the solvent vial contains an overfill.

- One 3 ml luer lock syringe with pre-attached 38 mm (1.5 inch) 21 gauge hypodermic safety needle with needle protection device.
- One 3 ml disposable syringe with luer lock tip.
- One vial adapter.
- One 25 mm (1 inch) 23 gauge hypodermic safety needle with needle protection device.
- One 38 mm (1.5 inch) 22 gauge hypodermic safety needle with needle protection device.
- One 51 mm (2 inch) 21 gauge hypodermic safety needle with needle protection device.
- Syringe and needle instructions.

Step 2: Reconstitution of the powder

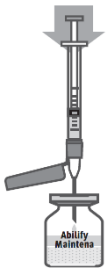
a) Remove the solvent and powder vial caps and wipe the tops with a sterile alcohol swab.

b) Using the syringe with pre-attached needle, withdraw the pre-determined solvent volume from the vial of the solvent into the syringe.

400 mg vial:

Add 1.9 mL solvent to reconstitute the powder.

A small amount of residual solvent will remain in the vial following withdrawal. Any excess should be discarded.

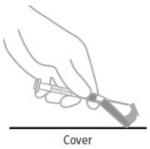


c) Slowly inject the solvent into the vial containing the powder.

d) Withdraw air to equalise the pressure in the vial by pulling back slightly on the plunger.

e) Subsequently, remove the needle from the vial.

Engage the needle safety device by using the onehanded technique.



Gently press the sheath against a flat surface until the needle is firmly engaged in the needle protection sheath.
Visually confirm that the needle is fully engaged into the needle protection sheath, and discard.

f) <u>Shake the vial vigorously for at least 30 seconds until the suspension appears uniform.</u>

g) Visually inspect the reconstituted suspension for particulate matter and discolouration prior to administration. The reconstituted medicine is a white to off-white, fluid suspension. Do not use if reconstituted suspension contains particulate matter or any discolouration.

h) If the injection is not performed immediately after reconstitution, keep the vial below 25 °C for up to 4 hours and shake it vigorously for at least 60 seconds to re-suspend prior to injection.

I) Do not store the reconstituted suspension in the syringe.

Step 3: Preparation prior to injection

a) Remove the cover, but not the adapter from the package.

b) Using the vial adapter package to handle the vial adapter, attach the pre-packaged luer lock syringe to the vial adapter.

c) Use the luer lock syringe to remove the vial adapter from the package and discard the vial adapter package. <u>Do not touch the spike tip of the adapter at any time.</u>

d) Determine the recommended volume for injection.

Aripiprazole Otsuka 400 mg vial

Dose	Volume to Inject
400 mg	2.0 mL
300 mg	1.5 mL
200 mg	1.0 mL
160 mg	0.8 mL

e) Wipe the top of the vial of the reconstituted suspension with a sterile alcohol swab.

f) Place and hold the vial of the reconstituted suspension on a hard surface. Attach the adapter-syringe assembly to the vial by holding the outside of the adapter and pushing the adapter's spike firmly through the rubber stopper, until the adapter snaps in place.

g) Slowly withdraw the recommended volume from the vial into the luer lock syringe to allow for injection.

<u>A small amount of excess product will remain in the vial.</u>

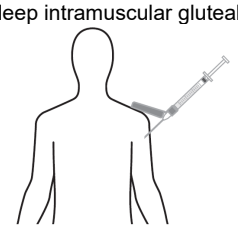
Step 4: Injection procedure

a) Detach the luer lock syringe containing the recommended volume of reconstituted Aripiprazole Otsuka suspension from the vial.
b) Select one of the following hypodermic safety needles depending on the injection site and patient's weight and attach the needle to the luer lock syringe containing the suspension for injection. Ensure the needle is firmly seated on the needle protection device with a push and clockwise twist and then pull the needle cap straight away from the needle.

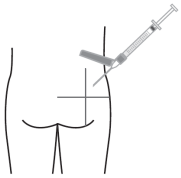
Body type	Injection site	Needle size
Non-obese	Deltoid Gluteal	25 mm (1 inch) 23 gauge 38 mm (1.5 inch) 22 gauge
Obese	Deltoid Gluteal	38 mm (1.5 inch) 22 gauge 51 mm (2 inch) 21 gauge

c) Slowly inject the recommended volume as a single intramuscular injection into the gluteal or deltoid muscle. Do not massage the injection site. Care must be taken to avoid inadvertent injection into the blood vessel. Do not inject into an area with signs of inflammation, skin damage, lumps and/or bruises.

For deep intramuscular gluteal or deltoid injection only.



deltoid



gluteal

Remember to rotate sites of injections between the two gluteal or deltoid muscles.
If initiating with the two injection start, inject into two different sites in two different muscles. DO NOT inject both injections concomitantly into the same deltoid or gluteal muscle.
For known CYP2D6 poor metabolisers administer in either two separate deltoid muscles or one deltoid and one gluteal muscle. DO NOT inject into two gluteal muscles.
Look for signs or symptoms of inadvertent intravenous administration.

Step 5: Procedures after injection

Engage the needle safety device as described in Step 2 e). Dispose of the vials, adapter, needles, and syringe appropriately after injection.
The powder and solvent vials are for single-use only.

PL 16378/1224

Revision date: 01.08.2025

Leaflet reference: ARI/ME/V3