Abilify Maintena contains the active substance aripiprazole and belongs to a group of medicines called antipsychotics. It 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 oral aripiprazole.

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 aripiprazole treatment. Tell your doctor immediately if you are having any thoughts or feelings about hurting yourself.

Before treatment with Abilify Maintena, tell your doctor if you suffer from

- 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
- cardiovascular diseases (diseases of the heart and circulation), family history of cardiovascular disease, stroke or "mini" stroke, abnormal blood pressure
- blood clots, or family history of blood clots, as antipsychotics have been associated with formation of blood clots
- 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.

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 plan to take any other medicines, including
medicines obtained without a prescription.

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, venlafaxine, St. John's Wort)
- antifungal medicines (such as ketoconazole, itraconazole)
- certain medicines to treat HIV infection (such as efavirenz, nevirapine, an protease inhibitors
e.g. indinavir, ritonavir)
- anticonvulsants used to treat epilepsy (such as carbamazepine, phenytoin, phenobarbital)
- certain antibiotics used to treat tuberculosis (rifabutin, rifampicin)

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 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 have received Abilify Maintena in the last trimester (last three months of their pregnancy):
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.

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 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.

Your doctor will decide on the dose of Abilify Maintena that is right for you. The recommended and starting dose is 400 mg unless your doctor decided to give you a lower starting or follow up dose (300 mg, 200 mg or 160 mg). Treatment with aripiprazole by mouth is continued for 14 days after the first injection. After that, treatment is given with injections of Abilify Maintena unless your doctor tells you otherwise.

If you are given more Abilify Maintena than you need
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 aripiprazole 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 have any further questions on the use of this medicine, ask your doctor or nurse.

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.

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.

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

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

- weight gain, weight loss
- feeling anxious, difficulty sleeping (insomnia)
- feeling restless and unable to keep still, difficulty sitting still, trembling, uncontrollable twitching, jerking or writhing movements, restless legs
- changes in your level of alertness, drowsiness
- 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; this is a medical term that includes several symptoms such as muscle stiffness, jerks when bending the limbs, slow or impaired body movements, no expression on the face, muscle tightness, shuffling, hurried steps and lack of normal arm movements when walking
- jerky resistance to passive movement as muscles tense and relax, abnormally increased muscle tone, muscle stiffness, slow body movement
- dizziness, headache
- dry mouth
- pain at the injection site, hardening of the skin at the injection site
- weakness, loss of strength or extreme tiredness
- high blood levels of the enzyme creatine phosphokinase
Uncommon side effects (may affect up to 1 in 100 people):

- decreased or increased appetite, distortion of the senses of taste and smell
- 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, decreased 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
- thoughts about suicide
- mental disorder characterized by defective or lost contact with reality, hallucination, delusion
- altered or increased sexual interest
- panic reaction, depression, affect lability, state of indifference with lack of emotion, feelings of emotional and mental discomfort, altered mood
- sleep disorder
- grinding of teeth or clenching of the jaw
- hiccups
- fixation of the eyeballs in one position, blurred vision, eye pain, double vision
- abnormal heartbeat, slow or fast heart rate, abnormal electrical conduction of the heart, abnormal reading (ECG) of the heart
- dizziness when getting up from a lying or sitting position due to a drop in blood pressure, high blood pressure
- cough
- upset stomach, indigestion, drooling, more saliva in mouth than normal, vomiting, nausea, diarrhoea, constipation, stomach ache or discomfort, frequent bowel movement
- abnormal liver blood values
- 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, gait disturbance, joint pain (arthralgia), back pain, decreased range of motion of joints, stiff neck, limited opening of mouth
- kidney stones, sugar (glucose) in urine
- enlargement of breast in men, breast tenderness, vaginal dryness
- loss of strength
- chest discomfort
- injection site reactions such as redness, swelling discomfort and injection site itching
- increased waist circumference

The following side effects have been reported since the marketing of oral aripiprazole but the frequency for them to occur is not known:

- low levels of white blood cells
- unusual heartbeat, sudden unexplained death, heart attack
- allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching, hives), rash
- ketoacidosis (ketones in the blood and urine) or coma, low sodium level in the blood
- loss of appetite (anorexia), difficulty in swallowing
- aggression
- nervousness, suicide attempt and suicide; speech disorder, seizure, serotonin syndrome (a reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles), combination of fever, muscle stiffness,
faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate (neuroleptic malignant syndrome)

- fainting, spasm of the muscles around the voice box, accidental inhalation of food with risk of pneumonia (lung infection), inflammation of the pancreas
- liver failure, inflammation of the liver, yellowing of the skin and white part of eyes, sensitivity to light, excessive sweating, stiffness or cramps, muscle pain, weakness
- involuntary loss of urine (incontinence), difficulty in passing urine
- prolonged and/or painful erection
- difficulty controlling core body temperature or overheating, chest pain, and swelling of hands, ankles or feet
- 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.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). 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. 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.

Do not throw away any medicines via wastewater. 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.
  - Each vial contains 300 mg aripiprazole.
  - After reconstitution each ml of suspension contains 200 mg 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, sodium dihydrogen phosphate monohydrate, sodium hydroxide
  - **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.

**Multipack**
Bundle pack of 3 single packs.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
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Gallions, Wexham Springs, Framewood Road,
Wexham, SL3 6PJ
United Kingdom

**Manufacturer**
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Denmark

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in October 2017.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
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 300 mg powder and solvent for prolonged-release suspension for injection**

**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.
   - 300 mg vial:
     - Add 1.5 ml solvent to reconstitute the powder.
   - 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 one-handed 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) Shake the vial vigorously for 30 seconds until the suspension appears uniform.


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. Do not touch the spike tip of the adapter at any time.
d) Determine the recommended volume for injection.

<table>
<thead>
<tr>
<th>Abilify Maintena 300 mg Vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>300 mg</td>
</tr>
<tr>
<td>200 mg</td>
</tr>
<tr>
<td>160 mg</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Abilify Maintena 400 mg Vial</th>
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</thead>
<tbody>
<tr>
<td>Dose</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>400 mg</td>
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<tr>
<td>300 mg</td>
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<tr>
<td>200 mg</td>
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<tr>
<td>160 mg</td>
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</tbody>
</table>

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.
   A small amount of excess product will remain in the vial.

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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.

<table>
<thead>
<tr>
<th>Body type</th>
<th>Injection site</th>
<th>Needle size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-obese</td>
<td>Deltoid</td>
<td>25 mm (1 inch) 23 gauge</td>
</tr>
<tr>
<td></td>
<td>Gluteal</td>
<td>38 mm (1.5 inch) 22 gauge</td>
</tr>
<tr>
<td>Obese</td>
<td>Deltoid</td>
<td>Gluteal</td>
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</tr>
<tr>
<td></td>
<td>38 mm (1.5 inch) 22 gauge</td>
<td>51 mm (2 inch) 21 gauge</td>
</tr>
</tbody>
</table>

**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 injection](image1)

![Gluteal injection](image2)

Remember to rotate sites of injections between the two gluteal or deltoid 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.