

## Aripiprazole 1mg/ml Oral Solution

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- The full name of this medicine is Aripiprazole 1mg/ml Oral Solution but within the leaflet it will be referred to as Aripiprazole Oral Solution.

### What is in this leaflet

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

#### 1. What Aripiprazole Oral Solution is and what it is used for

Aripiprazole Oral Solution contains the active substance aripiprazole and belongs to a group of medicines called antipsychotics. It is used to treat adults and adolescents aged 15 years and older who suffer from a disease characterised by 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 Oral Solution is used to treat adults and adolescents aged 13 years and older who suffer from a condition with symptoms such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. In adults it also prevents this condition from returning in patients who have responded to the treatment with Aripiprazole Oral Solution.

#### 2. What you need to know before you take Aripiprazole Oral Solution

##### Do not take Aripiprazole Oral Solution

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

##### Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Aripiprazole Oral Solution 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.
- Seizure.
- Involuntary, irregular muscle movements, especially in the face.
- Cardiovascular diseases, 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 of excessive gambling.

If you notice you are gaining weight, develop unusual movements, experience somnolence that interferes with normal daily activities, any difficulty in swallowing or allergic symptoms, please tell your doctor.

If you are an elderly patient suffering from dementia (loss of memory and other mental abilities), you or your carer/relative should tell your doctor if you have ever had a stroke or "mini" stroke.

Tell your doctor immediately if you are having any thoughts or feelings about hurting yourself. Suicidal thoughts and behaviours have been reported during aripiprazole treatment.

Tell your doctor immediately if you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heartbeat.

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.

Aripiprazole 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 in children and adolescents under 13 years of age. It is not known if it is safe and effective in these patients.

##### Other medicines and Aripiprazole Oral Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Blood pressure-lowering medicines: Aripiprazole Oral Solution 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.

Taking Aripiprazole Oral Solution with some medicines may require the need to change your dose of Aripiprazole Oral Solution. 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, 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 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
- selective-serotonin-reuptake-inhibitors (SSRIs) (such as paroxetine and fluoxetine) used for depression, OCD, panic and anxiety
- other anti-depressants (such as venlafaxine and tryptophan) used in major depression
- tricyclics (such as clomipramine and amitriptyline) used for depressive illness
- St John's Wort (*Hypericum perforatum*) used as a herbal remedy for mild depression
- pain killers (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 symptoms taking any of these medicines together with Aripiprazole Oral Solution, you should see your doctor.

##### Aripiprazole Oral Solution with food, drink and alcohol

Aripiprazole Oral Solution can be taken regardless of meals. However, the oral solution should not be diluted with other liquids or mixed with any food prior to administration. 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 taking this medicine.

The following symptoms may occur in newborn babies, of mothers that have used Aripiprazole Oral Solution 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 may need to contact your doctor.

Be sure to tell your doctor immediately if you are breast-feeding. If you are taking Aripiprazole Oral Solution, you should not breast-feed.

##### 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 Oral Solution contains propylene glycol and sodium benzoate

This medicine contains 81.4mg of propylene glycol and 1.0mg of sodium benzoate per 1ml of Aripiprazole Oral Solution.

##### Information on sodium content

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

#### 3. How to take Aripiprazole Oral Solution

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

##### The recommended dose for adults is 15ml solution

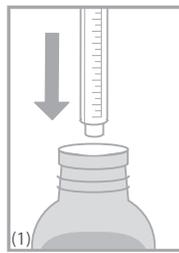
(corresponding to 15mg aripiprazole) once a day. However your doctor may prescribe a lower or higher dose to a maximum of 30mg (i.e. 30ml) once a day.

##### Use in children and adolescents

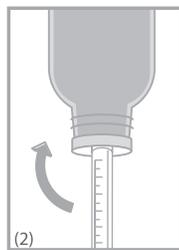
Aripiprazole may be started at a low dose using the oral solution (liquid) form. The dose may be gradually increased to the recommended dose for adolescents of 10mg once a day. However your doctor may prescribe a lower or higher dose to a maximum of 30mg once a day.

##### Measuring dose:-

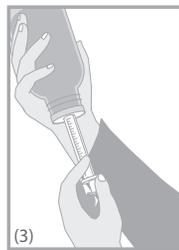
- Doses up to 5ml should be measured using the 5ml syringe supplied in the carton.
- Doses of 10ml and more should be measured using the measuring cup or the 5ml syringe supplied in the carton.



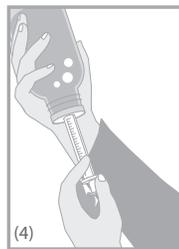
Open the bottle and make sure that the syringe is firmly inserted into the adaptor (Figure 1).



Turn the bottle upside down with the syringe still in place (Figure 2).



Pull the plunger down and fill the syringe with a quantity of solution slightly beyond the prescribed dose (Figure 3).



If any bubbles appear in the syringe, keep the bottle upside down and slightly push in the plunger and pull it back again. Repeat until there are no bubbles in the syringe (Figure 4).



Push the plunger in slowly to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 5).



Turn the bottle the right way up and remove the syringe (Figure 6).

Wash the syringe and the cup with water after use and close the bottle with the plastic screw cap.

If you have the impression that the effect of Aripiprazole Oral Solution is too strong or too weak, talk to your doctor or pharmacist.

**Try to take the Aripiprazole Oral Solution at the same time each day.** It does not matter whether you take it with or without food. However, you should not dilute with other liquids or mix with other food prior to taking Aripiprazole Oral Solution.

**Even if you feel better,** do not alter or discontinue the daily dose of Aripiprazole Oral Solution without first consulting your doctor.

**If you take more Aripiprazole Oral Solution than you should**

If you realise you have taken more Aripiprazole Oral Solution than your doctor has recommended (or if someone else has taken some of your Aripiprazole Oral Solution), contact your doctor right away. If you cannot reach your doctor, go to the nearest hospital and take the pack with you.

The following symptoms may occur: feeling unusually tired or sleepy, increased blood pressure, rapid heartbeat, feeling or being sick and diarrhoea. Serious signs and symptoms in children may include tiredness, fainting and abnormal body movements (called extrapyramidal symptoms).

**If you forget to take Aripiprazole Oral Solution**

If you miss a dose, take the missed dose as soon as you remember but do not take two doses in one day. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Aripiprazole Oral Solution**

Do not stop your treatment just because you feel better. It is important that you carry on taking Aripiprazole Oral Solution 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, pharmacist or nurse.

#### 4. Possible side effects

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

**Stop taking this medicine and contact your doctor immediately if you experience any of the following serious side effects:**

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

- feeling more thirsty or hungrier than usual, the need to urinate more often, feeling confused, weak, tired or your breath may smell fruity: these are signs of diabetes.

**Not known** (frequency cannot be estimated from the available data):

- severe itching of the skin (with raised lumps) or swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing or breathing (angioedema).
- severe 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).
- abnormal bruising, bleeding or signs of infection such as a sore throat and high temperature (can indicate reduced number of white blood cells or platelets).
- thoughts of suicide or suicide attempt.
- swelling, pain and redness in the leg indicating a blood clot in the veins, which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.
- life-threatening irregular heartbeat, heart attack, slower heartbeat.
- yellowing of the skin and white part of eyes (jaundice), dark urine, nausea, diarrhoea, tiredness, flu like symptoms, swollen abdomen, bleeding easily or confusion (can be symptoms of liver inflammation or liver failure).
- fever, muscle stiffness, muscle pains, vomiting, sweating, dark urine or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome").
- prolonged and/or painful erection.

**The following side effects could happen:**

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

- difficulty sleeping
- feeling anxious
- feeling restless and unable to keep still, difficulty sitting still
- uncontrollable twitching, jerking or writhing movements
- trembling
- headache
- tiredness
- sleepiness
- light-headedness
- shaking and blurred vision
- decreased number of or difficulty making bowel movements
- indigestion
- feeling sick
- more saliva in mouth than normal
- vomiting
- feeling tired.

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

- increased blood levels of the hormone prolactin
- too much sugar in the blood
- depression
- altered or increased sexual interest
- uncontrollable movements of mouth, tongue and limbs (tardive dyskinesia)
- muscle disorder causing twisting movements (dystonia)
- restless legs
- double vision, eye sensitivity to light
- fast heartbeat
- a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting
- hiccups.

**Not known** (frequency cannot be estimated from the available data):

- worsening of diabetes, ketoacidosis (ketones in the blood and urine) or coma
- not enough sodium in the blood
- loss of appetite (anorexia)

- weight loss
- weight gain
- feeling aggressive
- agitation
- nervousness
- seizure
- serotonin syndrome (a reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles)
- speech disorder
- sudden unexplained death
- high blood pressure
- fainting
- accidental inhalation of food with risk of pneumonia (lung infection)
- spasm of the muscles around the voice box
- fixation of the eyeballs in one position
- inflammation of the pancreas
- difficulty swallowing
- diarrhoea
- abdominal discomfort
- stomach discomfort
- reports of abnormal liver tests values
- skin rash
- sensitivity to light
- baldness
- excessive sweating
- abnormal muscle breakdown which can lead to kidney problems
- muscle pain
- stiffness
- involuntary loss of urine (incontinence)
- difficulty in passing urine
- withdrawal symptoms in newborn babies in case of exposure during pregnancy
- difficulty controlling core body temperature or overheating
- chest pain
- swelling of hands, ankles or feet
- in blood tests: fluctuating blood sugar, increased glycosylated haemoglobin
- 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.

In elderly patients with dementia, more fatal cases have been reported while taking aripiprazole. In addition, cases of stroke or "mini" stroke have been reported.

**Additional side effects in children and adolescents**

Adolescents aged 13 years and older experienced side effects that were similar in frequency and type to those in adults except that sleepiness, uncontrollable twitching or jerking movements, restlessness, and tiredness were very common (may affect more than 1 in 10 people) and upper abdominal pain, dry mouth, increased heart rate, weight gain, increased appetite, muscle twitching, uncontrolled movements of the limbs, and feeling dizzy, especially when getting up from a lying or sitting position, weight loss, increase in blood insulin levels, irregular heartbeat, signs of infection such as a sore throat and high temperature (can indicate reduced number of white blood cells or platelets) were common (may affect up to 1 in 10 people).

**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 Website: [www.mhra.gov.uk/yellowcard](http://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 Oral Solution

Keep this medicine out of the sight and reach of children. Do not take this medicine after the expiry date which is stated on the bottle and on the carton. The expiry date refers to the last day of that month. Do not refrigerate or freeze. Use within 6 months after first opening. Store in the original bottle in order to protect from light.

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 Aripiprazole Oral Solution contains**

The active substance is aripiprazole. Each ml contains 1mg of aripiprazole. The other ingredients are: Propylene glycol (E1520), Macrogol 4000, Phosphoric acid, Hypromellose 2910, Erythritol (E968), Sucralose (E955), Sodium benzoate (E211), Disodium edetate, N&A Flavour for grape 26436: Flavouring ingredients -Propylene glycol (E1520) and purified water.

**What Aripiprazole Oral Solution looks like and contents of the pack**

Aripiprazole 1mg/ml Oral Solution is a clear, colourless liquid supplied in amber coloured glass bottles containing 150ml per bottle.

Each bottle is closed with white plastic (polyethylene HD) "Child proof" screw cap with a white polyethylene adaptor (plug).

Each carton contains 1 bottle, a leaflet and two measuring devices, a 5ml oral syringe and a 30ml measuring cup.

The syringe body is made of PP and the plunger is made of HDPE and is graduated for dosing of 0.5ml and then every 0.5ml up to 5ml.

The measuring cup is made of PP and is graduated for dosing of 5ml, 10ml, 15ml, 20ml, 25ml up to a maximum volume of 30ml.

**Marketing Authorisation Holder**

Accord, Barnstaple, EX32 8NS, UK

**Manufacturer**

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