

Package leaflet: Information for the patient

Aripiprazole 1 mg/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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Aripiprazole is and what it is used for

Aripiprazole contains the active substance aripiprazole, which 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 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.

2. What you need to know before you take Aripiprazole

Do not take Aripiprazole:

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

Warnings and precautions

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.

Talk to your doctor or pharmacist before taking Aripiprazole if you suffer from or have ever suffered 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
- conditions which would lead to reduced blood pressure such as loss of fluid, reduced blood volume and use of blood pressure lowering medicines
- increased 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
- a condition known as Attention-deficit hyperactivity disorder (ADHD) (with symptoms such as difficulty in maintaining focus on one task, struggle to follow instructions, hyperactive) and are taking medicines to treat this condition.

During treatment

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

Tell your doctor if you suffer from shaking, decreased heart rate, muscle stiffness and balance disorders while on treatment with this medicine. These may be signs of a condition known as parkinsonism.

If you are an elderly patient suffering from Alzheimer's disease, 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. Your doctor may consider stopping your treatment with aripiprazole.

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

Aripiprazole is not recommended for use in children and adolescents under 13 years and for treating schizophrenia in children under 15 years. Ask your doctor or pharmacist for advice before taking Aripiprazole.

Other medicines and Aripiprazole

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

Blood pressure-lowering medicines: Aripiprazole 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.

If you are taking Aripiprazole with some other medicines, you may need to change your dose of Aripiprazole. It is especially important to mention the following to your doctor:

- quinidine (medicines to correct heart rhythm)
- escitalopram, fluoxetine (antidepressant), cimetidine (used to treat stomach ulcers) or herbal remedy used to treat depression and anxiety
- ketoconazole, itraconazole (antifungal agents)
- medicines that may cause changes in heart rhythm which may be seen in tests (such as alfuzosin, amiodarone, chloroquine)
- medicines that may alter the level of blood salts (such as hydrocortisone, prednisolone, furosemide)
- certain medicines to treat HIV infection (such as ritonavir, indinavir, nelfinavir, efavirenz, nevirapine)
- diltiazem, carbamazepine, phenytoin, phenobarbital, primidone (anticonvulsants used to treat epilepsy).
- rifampicin and rifabutin (antibiotic used to treat tuberculosis)

These medicines may increase the risk of side effects or reduce the effect of Aripiprazole if you get any unusual symptom taking any of these medicines together Aripiprazole 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
- selective-serotonin-reuptake-inhibitors (SSRIs) (such as paroxetine and fluoxetine) and selective-serotonin-noradrenalin-reuptake-inhibitors (SNRIs) (such as venlafaxine) used for depression, OCD, panic and anxiety
- tricyclic's (such as clomipramine and amitriptyline) used for depressive illness
- St John's Wort (*Hypericum perforatum*) used as an herbal remedy for mild depression
- 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, you should see your doctor.

Aripiprazole with alcohol

Alcohol should be avoided when taking Aripiprazole.

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 or pharmacist for advice before taking this medicine.

Pregnancy

The following symptoms may occur in newborn babies, of mothers that have used Aripiprazole 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.

Breast-feeding

If you are taking Aripiprazole, your doctor will discuss with you whether you should breastfeed 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 taking this medicine.

Driving and using machines

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

This medicine contains sodium benzoate

This medicine contains 1 mg sodium benzoate in each ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

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

This medicine contains propylene glycol

This medicine contains 80 mg propylene glycol in each ml of oral solution.

3. How to take Aripiprazole

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 10 ml or 15 ml solution (corresponding to 10 mg or 15 mg aripiprazole) once a day. However your doctor may prescribe a lower or higher dose to a maximum of 30 ml (i.e. 30 mg) once a day.

Elderly

If you are elderly your doctor may start your treatment with a dose lower than the recommended dose.

Patients with liver problems

Tell your doctor if you are suffering from severe liver problems as your doctor may need to adjust the dose of your medicine.

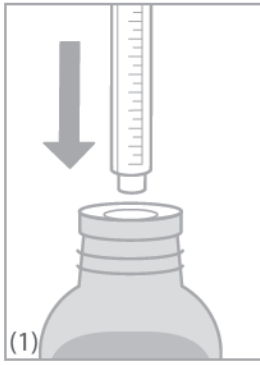
Use in children and adolescents

Aripiprazole may be started at a low dose with the oral solution (liquid) form. This should be given using the 5 ml graduated oral syringe supplied in the carton. The dose may be gradually increased to **the recommended dose for adolescents of 10 ml once a day.**

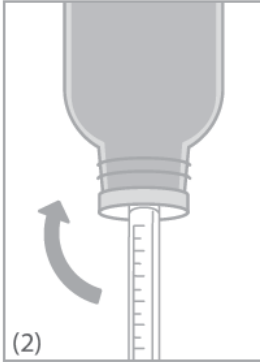
However your doctor may prescribe a lower or higher dose to a maximum of 30 ml once a day.

Measuring dose

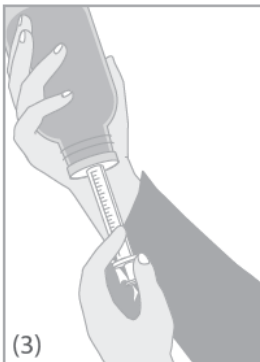
The dose of Aripiprazole oral solution must be measured using the graduated 30 ml cup or the 5 ml graduated oral syringe supplied in the carton.



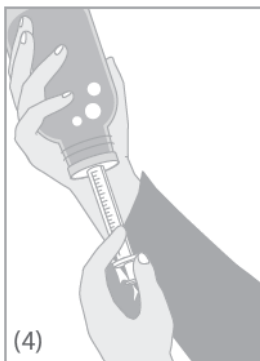
Open the bottle and make sure that the syringe is firmly inserted into the adaptor (Figure 1).



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



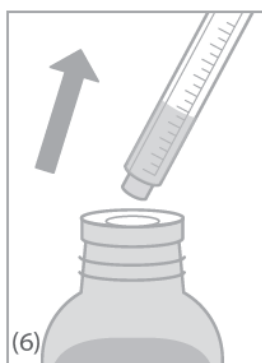
Pull the plunger down and fill the syringe with a quantity of solution slightly beyond the prescribed dose (Figure 3).



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 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 without first consulting your doctor.

If you take more Aripiprazole 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.

Patients who have taken too much aripiprazole have experienced the following symptoms:

- feeling sleepy or slow,
- increase in blood pressure, rapid heartbeat,
- feeling or being sick or diarrhoea.

In children, an overdose may cause:

- sleepiness,
- temporary loss of consciousness,
- movement and muscle control problems throughout the body (e.g. shaking, unusual movements of the body).

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

If you forget to take Aripiprazole

If you miss a dose, take the missed dose as soon as you remember but do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Stop taking Aripiprazole and contact your doctor immediately or go to your nearest hospital emergency room if you have any of the following:

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

- changes in the levels of some blood cells, which can be seen on a blood test and lead to getting more infections than normal
- heart attack
- unusual heart beat or abnormal heart rhythm which may be seen in tests
- allergic reaction (e.g. swelling in the mouth, tongue, face and throat, difficulty in breathing and swallowing, itching, rash)
- ketoacidosis (ketones in the blood and urine) or coma
- suicide, thoughts of suicide, suicide attempt
- seizures
- 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
- 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
- accidental inhalation of food with risk of pneumonia
- inflammation of the pancreas
- difficulty in passing urine (urinary retention)
- liver failure, inflammation of the liver, yellowing of the skin and white part of eyes
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown which can be life-threatening and lead to kidney problems.

Other possible side effects:

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

- uncontrollable twitching, jerking or writhing movements, restless legs
- feeling restless and unable to keep still, difficulty sitting still
- headache
- light-headedness
- sleepiness
- shaking
- tiredness
- diabetes mellitus

- feeling sick (nausea), being sick (vomiting), indigestion, constipation, increased production of saliva
- trouble sleeping, feeling anxious
- blurred vision.

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

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

The following side effects have been reported since the marketing of aripiprazole but the frequency for them to occur is not known (frequency cannot be estimated from the available data):

- sudden unexplained death
- decreased heart rate
- low sodium level in the blood
- weight gain
- weight loss
- loss of appetite (anorexia)
- nervousness
- agitation
- aggression
- speech disorder
- fixation of the eyeballs in one position
- fainting
- high blood pressure
- spasm of the muscles around the voice box
- difficulty in swallowing
- reduction in blood platelets resulting in bleeding or bruising more easily than normal
- reports of abnormal liver test values
- abdominal discomfort
- stomach discomfort
- diarrhoea
- skin rash
- skin sensitivity to light
- unusual hair loss or thinning
- excessive sweating
- serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia)
- stiffness or cramps
- muscle pain
- involuntary loss of urine
- prolonged and/or painful erection

- difficulty controlling core body temperature or overheating, chest pain, and swelling of hands, ankles or feet
- increased or fluctuating blood sugar and other changes which may be seen in blood tests.
- 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 (greater than 1 in 10 patients) 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, were common (greater than 1 in 100 patients).

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 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

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 bottle and on the carton after EXP. The expiry date refers to the last day of that month.

After first opening: Use within 6 months.

Do not refrigerate or freeze. Store in the original package 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 contains

The active substance is aripiprazole. Each ml contains 1 mg of aripiprazole.

The other ingredients are disodium edetate; erythritol (E 968); hypromellose; macrogol 4000; phosphoric acid, concentrated; propylene glycol (E 1520); sodium benzoate (E 211); sucralose (E 955); water, purified, grape flavour.

What Aripiprazole looks like and contents of the pack

Aripiprazole 1 mg/ml oral solution is a clear, colourless liquid.

Aripiprazole is supplied in amber glass bottles with child-resistant caps. Each bottle contains 150 ml of Aripiprazole, and is placed in a cardboard carton. Each carton also contains a 5 ml syringe (graduated at every 0.5 ml) and a 30 ml measuring cup (graduated at every 5 ml).

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturer

Balkanpharma – Troyan AD, 1 Krayrechna Str., Troyan, 5600, Bulgaria.

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