

Package leaflet: Information for the patient

<Product name> 5 mg tablets

<Product name> 10 mg tablets

<Product name> 15 mg tablets

Aripiprazole

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

1. What <Product name> is and what it is used for

<Product name> is one of 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.

<Product name> 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 <Product name>.

2. What you need to know before you take <Product name>

Do not take <Product name>

- 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 pharmacist before taking <Product name> 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.

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.

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 heart beat.

Children and adolescents

<Product name> is not for use in children and adolescents under 13 years. Ask your doctor or pharmacist for advice before taking <Product name>.

Other medicines and <Product name>

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

Blood pressure-lowering medicines: <Product name> 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 <Product name> with some medicines may need to change your dose of <Product name>. It is especially important to mention the following to your doctor:

- Medicines to correct heart rhythm
- Antidepressants or herbal remedy used to treat depression and anxiety
- Antifungal agents
- Certain medicines to treat HIV infection
- Anticonvulsants used to treat epilepsy

Medicines that increase the level of serotonin: triptans, tramadol, tryptophan, SSRIs (such as paroxetine and fluoxetine), tricyclics (such as clomipramine, amitriptyline), pethidine, St John's Wort and venlafaxine. These medicines increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with <Product name>, you should see your doctor.

<Product name> with food, drink and alcohol

<Product name> can be taken regardless of meals.

Alcohol should be avoided when taking <Product name>.

Pregnancy and breast-feeding

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. The following symptoms may occur in newborn babies, of mothers that have used <Product name> 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 <Product name>, you should not breast-feed.

Driving and using machines

Do not drive or use any tools or machines, until you know how <Product name> affects you.

<Product name> contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take <Product name>

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

Use in children and adolescents

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

If you have the impression that the effect of <Product name> is too strong or too weak, talk to your doctor or pharmacist.

Try to take the <Product name> tablet at the same time each day. It does not matter whether you take it with or without food. Always take the tablet with water and swallow it whole.

Even if you feel better, do not alter or discontinue the daily dose of <Product name> without first consulting your doctor.

If you take more <Product name> than you should

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

If you forget to take <Product name>

If you miss a dose, take the missed dose as soon as you remember but do not take two doses in one day.

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.

Common side effects (may affect up to 1 in 10 people): uncontrollable twitching or jerking movements, headache, tiredness, nausea, vomiting, an uncomfortable feeling in the stomach, constipation, increased production of saliva, light-headedness, trouble sleeping, restlessness, feeling anxious, sleepiness, shaking and blurred vision.

Uncommon side effects (may affect up to 1 in 100 people): some people may feel dizzy, especially when getting up from a lying or sitting position, or may experience a fast heart rate or double vision.

Some people may feel depressed. Some people may experience altered or increased sexual interest.
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):

Changes in the levels of some blood cells; unusual heart beat, sudden unexplained death, heart attack; allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching, rash); high blood sugar, onset or worsening of diabetes, ketoacidosis (ketones in the blood and urine) or coma, low sodium level in the blood; weight gain, weight loss, anorexia; nervousness, agitation, feeling anxious, excessive gambling; thoughts of suicide, suicide attempt and suicide, aggression; 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; fainting, high blood pressure, 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 (if you notice any of these symptoms, seek medical advice immediately); spasm of the muscles around the voice box, accidental inhalation of food with risk of pneumonia, difficulty in swallowing; inflammation of the pancreas; liver failure, inflammation of the liver, yellowing of the skin and white part of eyes, reports of abnormal liver test values, abdominal and stomach discomfort, diarrhoea; fixation of the eyeballs in one position; skin rash and sensitivity to light, unusual hair loss or thinning, excessive sweating; stiffness or cramps, muscle pain, weakness; involuntary loss of urine, 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.

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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

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

This medicine does not require any special temperature storage conditions.
Store in the original package in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the blister and on the carton after "EXP". The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What <Product name> contains

- <Product name> 5 mg tablets: The active substance is aripiprazole. Each tablet contains 5 mg of aripiprazole.
The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, hydroxypropylcellulose, crospovidone type A, Silica colloidal anhydrous, magnesium stearate, indigo carmine aluminium lake (E132).
- <Product name> 10 mg tablets: The active substance is aripiprazole. Each tablet contains 10 mg of aripiprazole.
The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, hydroxypropylcellulose, crospovidone type A, Silica colloidal anhydrous, magnesium stearate, iron oxide red (E172).
- <Product name> 15 mg tablets: The active substance is aripiprazole. Each tablet contains 15 mg of aripiprazole.
The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, hydroxypropylcellulose, crospovidone type A, Silica colloidal anhydrous, magnesium stearate, iron oxide yellow (E172).

What <Product name> looks like and contents of the pack

<Product name> 5 mg tablets are blue colour, modified rectangular shaped, uncoated mottled tablets debossed with '250' on one side and plain on other side.

<Product name> 10 mg tablets are pink colour, modified rectangular shaped, uncoated mottled tablets debossed with '252' on one side and plain on other side.

<Product name> 15 mg tablets are yellow colour, round shaped, bevelled edge, uncoated mottled tablets debossed with '253' on one side and plain on other side.

Tablets are supplied in blisters packed in cartons containing 7, 10, 14, 28, 30, 35, 40, 56, 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder and Manufacturer

PRO.MED.CS Praha a.s., Telčská 377/1, Michle, 140 00 Praha 4, Czech Republic

This leaflet was last revised in

<[To be completed nationally]>