Package leaflet: Information for the user
Aripiprazole 5 mg tablets
Aripiprazole 10 mg tablets
Aripiprazole 15 mg tablets
Aripiprazole 30 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 give it to anyone else. 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 mentioned 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. It 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, suspicious ideas, delusions, 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 already had a single episode of the condition.

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.
- Difficulty in feeding.
- If you have the impression that the effect of Aripiprazole is too strong or too weak, talk to your doctor.

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
Talk to your doctor before taking Aripiprazole if you suffer from
- High blood sugar (characterised by symptoms such as thirst, passing large amounts of urine, increase in appetite, and feeling weak) or family history of diabetes
- Seizures
- Irregular involuntary muscle movements, such as tremors or stiffness
- Cardiovascular diseases, family history of cardiovascular diseases, 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
- 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 fall. Caution should be taken, particularly if you are an elderly patient or have some debility.

If you notice you are gaining weight, develop unusual movements, experience somnolence that interferes with normal daily activities or 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 or other people. This medicine may cause feelings of hopelessness and suicidal thoughts. Suicidal thoughts and behaviours have been reported during the initial 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.

Children and adolescents
Do not use this medicine in children and adolescents under 15 years of age. It is not known if it is safe and effective in these patients.

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 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
This medicinal product may be started at a low dose with the oral solution (list the recommended dose for children and 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 Aripiprazole is too strong or too weak, talk to your doctor or pharmacist.

Try to take your Aripiprazole 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 Aripiprazole without first consulting your doctor.

If you take more Aripiprazole than you should

If you realise you have taken more Aripiprazole tablets than your doctor has recommended (or if someone else has taken some of your Aripiprazole 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 Aripiprazole

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 stop taking Aripiprazole

Do not stop your treatment just because you feel better. It is important that you carry on taking your Aripiprazole 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 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):
- Diabetes mellitus,
- Difficulty sleeping,
- Feeling anxious,
- Feeling restless and unable to keep still, difficulty sitting still,
- Uncontrollable twitching, jerking or writhing movements, restless legs,
- Trembling,
- Headache,
- Tiredness,
- Sleepiness,
- Light-headedness,
- Shaking or blurred vision,
- Decreased number of or difficulty making bowel movements,
- Feeling sick,
- Muscle twitching 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),
- Double vision, eye sensitivity to light,
- Fast heart beat,
- A fall in blood pressure on standing up which causes dizziness, light-headedness or fainting,
- Hiccups.

The following side effects have been reported since the marketing of Aripiprazole but the frequency for them to occur is not known.
- Low levels of white blood cells,
- Loss of blood platelets,
- Allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching, hives),
- Onset or worsening of diabetes, ketoacidosis (ketones in the blood and urine or coma),
- High blood sugar,
- Not enough sodium in the blood,
- Loss of appetite (anorexia),
- Weight loss,
- Weight gain,
- Thoughts of suicide, suicide attempt and suicide,
- Excessive gambling,
- Feeling agressive,
- Agitation,
- Nervousness,
- Combination of fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate, fasting (neuropsychiatric malignant syndrome),
- Seizure,
- Serotonin syndrome (a reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles),
- Dizziness,
- Sudden unexplained death,
- Life-threatening irregular heart beat,
- Heart attack,
- Slower heart beat,
- 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),
- High blood pressure,
- Fainting,
- Accidental inhalation of food with risk of suffocation (asphyxiation),
- Spasm of the muscles around the voice box,
- Inflammation of the pancreas,
- Difficulty swallowing,
- Diarrhoea,
- Abdominal discomfort,
- Stomach ulcer discomfort,
- Liver failure,
- Inflammation of the liver,
- Yeast infection of the skin and white part of eyes,
- Reports of abnormal liver tests values,
- Skin rash,
- Seizures while light, effect of light
- Baldness,
- Excessive sweating,
- Abnormal muscle breakdown which can lead to kidney problems,
- Muscle pain,
- More saliva,
- Involuntary loss of urine (incontinence),
- Difficulty in passing urine,
- Withdrawal symptoms in newborn babies in case of exposure during pregnancy,
- Prolonged and/or painful erection,
- Difficulty controlling core body temperature or overheating,
- Chest pain,
- Swelling of hands, ankles or feet,
- In blood tests: fluctuating blood sugar, increased glycylated haemoglobin,
- fixation of the eyeballs in one position
- In elderly patients with dementia, more fatal cases were 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 uncontrollably 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, uncontrollable 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 Yellow Card Scheme Website: 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 label.

The medicinal product does not require any special storage conditions.

6. Contents of the pack and other information
What Aripiprazole contains
- The active substance is aripiprazole.
- Each tablet contains 5 mg of aripiprazole.
- Each tablet contains 10 mg of aripiprazole.
- Each tablet contains 30 mg of aripiprazole.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, indigo carmine aluminium lake (E132) (for 5 mg strength only), hydroxypropyl cellulose, silica colloidal anhydrous, magnesium stearate.

What Aripiprazole looks like and contents of the pack
Tablet:
Aripiprazole 5 mg tablets
Blue colored, modified rectangular shaped, uncoated tablets debossed with "02" on one side and 'H' on other side. The size is 8 mm x 4.5 mm.
Aripiprazole 10 mg tablets
White colored, modified rectangular shaped, uncoated tablets debossed with "02" on one side and 'H' on other side. The size is 8 mm x 4.5 mm.
Aripiprazole 15 mg tablets
White colored, rounded shaped (diameter 7 mm), uncoated tablets debossed with '04' on one side and 'H' on other side.
Aripiprazole 30 mg tablets
White colored, round shaped (diameter 9 mm), uncoated tablets debossed with '06' on one side and 'H' on other side.

Aripiprazole tablets are available in Polyamide/Aluminium PVC/Aluminium foil blister pack and HDPE bottle with polypropylene closure containing silica gel as desiccant.

Pack sizes:
Blister packs: 14, 28, 30, 39, 56 and 98 tablets
HDPE bottle packs: 30, 100, 250 and 500 tablets
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6DG
United Kingdom
Manufacturer
APL Swift Services (Malta) Limited
HAF2, Hal Far Industrial Estate, Hal Far
Brzezbugia, BBG 3000
Malta
or
Milpharm Limited
Ares Block, Odyssey Business Park
West End Road
Ruislip HA4 6DG
United Kingdom
This leaflet was last revised in 05/2020.