

Package leaflet: Information for the user
Aripiprazole Milpharm 5 mg tablets
Aripiprazole Milpharm 10 mg tablets
Aripiprazole Milpharm 15 mg tablets
Aripiprazole Milpharm 30 mg tablets
aripiprazole

Read all of this leaflet carefully before you start using 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 Milpharm is and what it is used for
2. What you need to know before you take Aripiprazole Milpharm
3. How to take Aripiprazole Milpharm
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1. What Aripiprazole Milpharm is and what it is used for

Aripiprazole Milpharm 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.

2. What you need to know before you take Aripiprazole Milpharm

Do not take Aripiprazole Milpharm

- 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 Milpharm 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 heart beat.

Children and adolescents

Do not use this medicine in children and adolescents under 13 years of age. It is not known if it is safe and effective in these patients. Ask your doctor or pharmacist for advice before taking Aripiprazole Milpharm.

Other medicines and Aripiprazole Milpharm

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

Blood pressure-lowering medicines: Aripiprazole Milpharm 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 Milpharm with some medicines may need to change your dose of Aripiprazole Milpharm. 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 Aripiprazole Milpharm, you should see your doctor.

Aripiprazole Milpharm with food, drink and alcohol

Aripiprazole Milpharm can be taken regardless of meals.

Alcohol should be avoided when taking Aripiprazole Milpharm.

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 Milpharm 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 Milpharm, you should not breast-feed.

Driving and using machines

Do not drive or use any tools or machines, until you know how Aripiprazole Milpharm affects you.

Aripiprazole Milpharm contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Aripiprazole Milpharm

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 (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 Aripiprazole Milpharm is too strong or too weak, talk to your doctor or pharmacist.

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

If you take more Aripiprazole Milpharm than you should

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

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 Milpharm

Do not stop your treatment just because you feel better. It is important that you carry on taking your Aripiprazole Milpharm tablets 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 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),
- double vision,
- 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 oral aripiprazole but the frequency for them to occur is not known:

- low levels of white blood cells,
- low levels 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 aggressive,
- agitation,
- nervousness,
- combination of fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate, fainting (neuroleptic 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),
- speech disorder,
- 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 pneumonia (lung infection),
- spasm of the muscles around the voice box,
- inflammation of the pancreas,
- difficulty swallowing,
- diarrhoea,
- abdominal discomfort,
- stomach discomfort,
- liver failure,
- inflammation of the liver,
- yellowing of the skin and white part of eyes,
- 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,
- 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 glycosylated haemoglobin.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aripiprazole Milpharm

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

The medicinal product does not require any special storage conditions.

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 Milpharm contains

- The active substance is aripiprazole.
Each tablet contains 5 mg of aripiprazole.
Each tablet contains 10 mg of aripiprazole.
Each tablet contains 15 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 Milpharm looks like and contents of the pack

Tablet.

Aripiprazole Milpharm 5 mg tablets

Blue colored, modified rectangular shaped, uncoated tablets debossed with '62' on one side and 'H' on other side. The size is 8 mm x 4.5 mm.

Aripiprazole Milpharm 10 mg tablets

White colored, modified rectangular shaped, uncoated tablets debossed with '63' on one side and 'H' on other side. The size is 8 mm x 4.5 mm.

Aripiprazole Milpharm 15 mg tablets

White colored, round shaped (diameter 7 mm), uncoated tablets debossed with '64' on one side and 'H' on other side.

Aripiprazole Milpharm 30 mg tablets

White colored, round shaped (diameter 9 mm), uncoated tablets debossed with '66' on one side and 'H' on other side.

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

Pack sizes:

Blister packs: 14, 28, 30, 49, 56 and 98 tablets

HDPE bottle packs: 30, 100, 250 and 500 tablets

Not all pack sizes may be marketed.

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