

Package leaflet: Information for the patient
Aripiprazole 20mg and 30mg Orodispersible Tablets

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 20mg and 30mg Orodispersible Tablets but within the leaflet it will be referred to as Aripiprazole tablets.

What is in this leaflet

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

1. What Aripiprazole tablets are and what they are used for

Aripiprazole tablets contain the active substance aripiprazole which belongs to a group of medicines called antipsychotics.

This medicine 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 tablets are 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 tablets.

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

Do not take Aripiprazole tablets

- 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 tablets.

Before treatment with Aripiprazole tablets, tell your doctor 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
- 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
- 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 this medicine 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 tablets

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 tablets 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.

When taking Aripiprazole tablets with some medicines, you may need to change your dose of Aripiprazole tablets or the other medicines. 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).

These medicines may increase the risk of side effects or reduce the effect of Aripiprazole; if you get any unusual symptoms taking any of these medicines together with Aripiprazole tablets, 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, OCD and social phobia as well as migraine and pain
- 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 increase the risk of side effects; if you get any unusual symptoms taking any of these medicines together with Aripiprazole tablets, you should see your doctor.

Aripiprazole tablets with food, drink and alcohol

This medicine can be taken regardless of meals.
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 tablets 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 need to contact your doctor.

If you are taking Aripiprazole tablets, your doctor will discuss with you whether you should breast-feed 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, for example when driving a car or handling machines.

Aripiprazole tablets contain aspartame

This medicine contains 6mg aspartame in each 20mg orodispersible tablet and 9mg aspartame in each 30mg orodispersible tablet.

Aspartame is a source of phenylalanine. **It may be harmful if you have phenylketonuria (PKU)**, a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Information on sodium content

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

3. How to take Aripiprazole tablets

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 15mg once a day. However, your doctor may prescribe a lower or higher dose to a maximum of 30mg 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 10mg once a day.** However, your doctor may prescribe a lower or higher dose to a maximum of 30mg once a day.

If you have the impression that the effects of your Aripiprazole tablets are too strong or too weak, talk to your doctor or pharmacist.

Try to take the Aripiprazole tablet at the same time each day. It does not matter whether you take it with or without food.

Immediately upon opening the blister, using dry hands, remove the tablet and place the entire orodispersible tablet on the tongue. Tablet disintegration occurs rapidly in saliva. The orodispersible tablet can be taken with or without liquid. Alternatively, disperse the tablet in water and drink the resulting suspension.

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

If you take more Aripiprazole tablets 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.

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

- rapid heartbeat, agitation/aggressiveness, problems with speech
- unusual movements (especially of the face or tongue) and reduced level of consciousness.

Other symptoms may include:

- acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing, sweating
- muscle stiffness, drowsiness or sleepiness, slower breathing, choking, high or low blood pressure, abnormal rhythms of the heart.

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

If you forget to take Aripiprazole tablets

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 tablets

Do not stop your treatment just because you feel better. It is important that you carry on taking Aripiprazole 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, 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 (may affect up to 1 in 10 people):

- feeling more thirsty or hungrier than usual, 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)
- 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
- 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, rash, swelling of the face, enlarged lymph nodes and kidney or liver injury (a hypersensitivity reaction called 'Drug Reaction with Eosinophilia and systemic symptoms' or 'DRESS')
- 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 (may affect up to 1 in 10 people):**

- difficulty sleeping
- feeling anxious
- feeling restless and unable to keep still, difficulty sitting still
- uncontrollable twitching or jerking 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 (may affect up to 1 in 100 people):

- increased or decreased 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
- fast heartbeat
- a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting
- hiccups
- eye sensitivity to light.

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

- 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
- suicide
- 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
- life-threatening irregular heartbeat
- heart attack
- slower heartbeat
- 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
- 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; they 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, 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 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 tablets

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 blister and on the carton. 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 Aripiprazole tablets contain

- The active substance is aripiprazole Each orodispersible tablet contains 20mg or 30mg of aripiprazole.
- The other ingredients are Silicified microcrystalline cellulose, Aspartame (E951), Vanilla flavour (501469 TP0551), Magnesium stearate, Croscarmellose sodium (E468).
Yellow iron oxide (E172) for 30mg orodispersible.

What Aripiprazole tablets look like and contents of the pack

Orodispersible tablet 20 mg

Round and white, 9 mm with "3" debossed on one side and "ZT" on the other.

Orodispersible tablet 30 mg

Round and yellow mottled, 10.5 mm with "4" debossed on one side and "ZT" on the other.

Pack sizes:

Blisters:

- Push-through blisters packed in cartons containing 28 orodispersible tablets.

Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

Manufacturer

Actavis Ltd.

BLB016

Bulebel Industrial Estate

Zejtun ZTN 3000

Malta

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