Package leaflet: Information for the patient

Aripiprazol Sandoz® 10 mg orodispergeerbare tabletten
Aripiprazol Sandoz® 15 mg orodispergeerbare tabletten
Aripiprazol Sandoz® 30 mg orodispergeerbare tabletten

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 [Nationally completed name] is and what it is used for

[Nationally completed name] contains the active substance aripiprazole and belong 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.

[Nationally completed 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 [Nationally completed name].

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed 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 before taking [Nationally completed name].

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.

Before treatment with [Nationally completed name], 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 with 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 [Nationally completed name]
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: [Nationally completed 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 [Nationally completed name] with some medicines may mean the doctor will need to change your dose of [Nationally completed name] 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, an 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 [Nationally completed name], if you get any unusual symptom taking any of these medicines together with [Nationally completed name] 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) used for depression, OCD, panic and anxiety
- other anti-depressants (such as venlafaxine and tryptophan) used in major depression
- tricyclic's (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 zolmitripitan) used for treating migraine

These medicines may increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with [Nationally completed name], you should see your doctor.

[Nationally completed name] 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 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.

If you are taking [Nationally completed name], 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, e.g. when driving a car or handling machines.

[Nationally completed name] contains lactose, sodium, aspartame and benzyl alcohol

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

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

10 mg:
This medicine contains 1.0 mg aspartame in each 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.

This medicine contains up to 0.0036 mg benzyl alcohol in each orodispersible tablet. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you have a liver or kidney disease or if you are pregnant or breast feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

15 mg:
This medicine contains 1.5 mg aspartame in each 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.

This medicine contains up to 0.0054 mg benzyl alcohol in each orodispersible tablet. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you have a liver or kidney disease or if you are pregnant or breast feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

30 mg:
This medicine contains 3.0 mg aspartame in each 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.

This medicine contains up to 0.0108 mg benzyl alcohol in each orodispersible tablet. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you have a liver or kidney disease or if you are pregnant or breast feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

3. How to take [Nationally completed 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.

<For MSs where 10 mg is not registered:>
This medicinal product is not available in 10 mg strength, therefore in case a strength lower than 15 mg is required, another medicinal product containing aripiprazole should be used.

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 medicine may be started at a low dose with theoral 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 [Nationally completed name] is too strong or too weak, talk to your doctor or pharmacist.

Try to take [Nationally completed name] at the same time each day. It does not matter whether you take it with or without food.

Do not open the blister until ready to administer. For single tablet removal, open the package and peel back the foil on the blister to expose the tablet. Do not push the tablet through the foil because this could damage the tablet. 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 [Nationally completed name]

without first consulting your doctor.

If you take more [Nationally completed name] than you should
If you realise you have taken more [Nationally completed name] than your doctor has recommended (or if someone else has taken some of your [Nationally completed name]), 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, and 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 [Nationally completed 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 stop taking [Nationally completed name]
Do not stop your treatment just because you feel better. It is important that you carry on taking [Nationally completed name] 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,

- akathisia (an uncontrollable feeling of inner restlessness and a compelling need to move constantly),
- uncontrollable twitching, jerking or writhing 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 side effects (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,
- eye sensitivity to light,
- fast heartbeat,
- 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,
- 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,
- fixation of the eyeballs in one position,
- sudden unexplained death,
- life-threatening irregular heartbeat,
- heart attack,
- slower heartbeat,
- 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,
- skin sensitivity to light,
- baldness,
- 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),
- 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: increased or 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; 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 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 [Nationally completed name]

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 carton after "EXP". The expiry date refers to the last day of that month.

This medicine 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 [Nationally completed name] contains

- The active substance is aripiprazole. Each orodispersible tablet contains 10 mg of aripiprazole.
  Each orodispersible tablet contains 15 mg of aripiprazole.
  Each orodispersible tablet contains 30 mg of aripiprazole.

- The other ingredients are:
  10 mg and 30 mg:
  lactose monohydrate, microcrystalline cellulose (E 460), croscarmellose sodium, silica colloidal anhydrous, aspartame (E 951), magnesium stearate (E 470b), iron oxide red (E 172), vanilla flavour (containing maltodextrin, gum arabic, propylene glycol, benzyl alcohol, vanilla flavouring).
  15 mg:
  lactose monohydrate, microcrystalline cellulose (E 460), croscarmellose sodium, silica colloidal anhydrous, aspartame (E 951), magnesium stearate (E 470b), iron oxide yellow (E 172), vanilla flavour (containing maltodextrin, gum arabic, propylene glycol, benzyl alcohol, vanilla flavouring).

See section 2, [Nationally completed name] contains lactose, sodium, aspartame and benzyl alcohol.

What [Nationally completed name] looks like and contents of the pack
10 mg:
Round, flat, pink tablets, engraved with '10' on one side and plain on the other with a diameter of 8.0

mm ± 0.1 mm.
15 mg:
Round, flat, yellow tablets, engraved with '15' on one side and plain on the other with a diameter of 9.0 mm ± 0.1 mm.
30 mg:
Round, flat, pink tablets, engraved with '30' on one side and plain on the other with a diameter of 10.0 mm ± 0.1 mm.

The orodispersible tablets are packed in peelable paper/PET/aluminium//PVC/aluminium/oPA blisters and inserted in a carton.

Pack sizes:
Blister: 10, 14, 28, 30, 49, 56, 98 orodispersible tablets
Unit dose blister: 10 x 1, 14 x 1, 28 x 1, 30 x 1, 49 x 1, 56 x 1, 98 x 1 orodispersible tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikanten:
Rontis Hellas Medical and Pharmaceutical Products S.A.
P.O.Box 3012 Larissa Industrial Area, Larissa, 41500,
Griekenland

GENEPHARM S.A.
18th km Marathonos Ave,
Pallini Attiki, 15351,
Griekenland

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
39179 Barleben,
Duitsland

Lek Pharmaceuticals d.d.

Verovškova ulica 57
Ljubljana, 1526
Slovenië

Dit medicijn is in het register ingeschreven onder:

Aripiprazol Sandoz 10 mg orodispergeerbare tabletten	RVG 115588
Aripiprazol Sandoz 15 mg orodispergeerbare tabletten	RVG 115589
Aripiprazol Sandoz 30 mg orodispergeerbare tabletten	RVG 115590

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

België:	Aripiprazole Sandoz 10 mg, 15 mg, 30 mg, orodispergeerbare tabletten
Duitsland:	Aripiprazol HEXAL 10 mg, 15 mg, 30 mg Schmelztabletten
Frankrijk:	ARIPIPRAZOLE SANDOZ 10 mg, 15 mg, 30 mg, comprimé orodispersible
Italië:	Aripiprazolo Sandoz GmbH
Luxemburg:	Aripiprazol Sandoz 10 mg, 15 mg, 30 mg comprimés orodispersibles
Nederland:	Aripiprazol Sandoz 10 mg, 15 mg, 30 mg orodispergeerbare tabletten
Oostenrijk:	Aripiprazol Sandoz 10 mg, 15 mg, 30 mg – Schmelztabletten
Polen:	Aripiprazole Sandoz
Slovenië:	Aripiprazol Sandoz 10 mg, 15 mg, 30 mg orodisperzibilne tablete
Slowakije:	Aripiprazol Sandoz 10 mg, 15 mg, orodispergovateľné tablety
Spanje:	Aripiprazol Flas Sandoz 10 mg, 15 mg, 30 mg comprimidos bucodispersables EFG
Tsjechië:	Aripiprazol Sandoz 10 mg, 15 mg tablety dispergovatelné v ústech

Deze bijsluiter is voor het laatst goedgekeurd in april 2024.