

ARIPIPRAZOLE SANDOZ®

Aripiprazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Aripiprazole Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking Aripiprazole Sandoz against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What Aripiprazole Sandoz is used for

What it does

Aripiprazole Sandoz is used to treat symptoms of schizophrenia.

Schizophrenia is a mental illness with disturbances in thinking, feelings and behaviour.

It contains the active ingredient aripiprazole and belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive. This

medicine is available only with a doctor's prescription.

Aripiprazole Sandoz is not recommended for use in children under the age of 18, as safety and efficacy have not been established in this age group.

Before you take Aripiprazole Sandoz

When you must not take Aripiprazole Sandoz

Do not take Aripiprazole Sandoz if you have an allergy to:

- aripiprazole the active ingredient or to any of the ingredients listed at the end of this leaflet under product description
- any other similar medicines.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take Aripiprazole Sandoz

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- a reaction to some medicines with a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure, which may lead to coma. This reaction is called neuroleptic malignant syndrome.
- a reaction to some medicines with abnormal movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaw which may progress to the arms and legs. This reaction is called tardive dyskinesia.
- low blood pressure
- problems with your heart or blood vessels
- epilepsy, seizures or fits
- problems with your oesophagus (food pipe) such as difficulty in swallowing
- high blood sugar or diabetes mellitus
- Alzheimer's disease or dementia
- alcohol or drug abuse or dependence or a history of one of these.
- venous thromboembolism or are at risk of venous thromboembolism
- have a history of or are at risk of sleep apnoea (a sleep disorder where your breathing is interrupted during sleep)

- lactose tolerance.

Tell your doctor if you are pregnant or plan to become pregnant.

Aripiprazole Sandoz is not recommended for use during pregnancy. If you need to take it during your pregnancy, your doctor will discuss with you the benefits and risks of taking it. Babies exposed to antipsychotics (including Aripiprazole Sandoz) during the third trimester of pregnancy are at risk of experiencing shaking, muscle stiffness, difficulty in feeding and/or withdrawal symptoms.

These symptoms may resolve spontaneously or require additional medical treatment.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

It is recommended that you do not breast-feed while taking Aripiprazole Sandoz, as it may pass into breast milk and therefore there is a possibility that your baby may be affected.

Tell your doctor if you drink alcohol.

Your doctor may advise you to avoid alcohol as it can magnify the side-effects of this medicine.

Tell your doctor if you have past experience of excessive gambling.

If you have not told your doctor about any of the above, tell him/her before you start taking Aripiprazole Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Aripiprazole Sandoz may interfere with each other. These include:

- medicines used to treat brain disorders such as, anxiety, depression, mood swings,

epilepsy or seizures, Parkinson's disease or insomnia

- medicines used to treat high blood pressure
- medicines used to treat fungal infections
- medicines used to treat heart rhythm disturbances
- medicines used to treat bacterial or viral infections
- a medicine called ciclosporin (Cysporin®; Neoral®; Sandimmun®)
- a medicine called cimetidine (Tagamet®; Magicul®; Sigmétadine®).

These medicines may be affected by Aripiprazole Sandoz, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Eating grapefruit or drinking grapefruit juice may affect how Aripiprazole Sandoz works.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking this medicine.

How to take Aripiprazole Sandoz

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much you will need to take each day. This will depend on your condition and whether you are taking any other medicines.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

The label put on the carton by the pharmacist will tell you how much you should take. If you take the wrong dose, Aripiprazole Sandoz may not work as well and your problem may not improve.

If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.

How to take it

Aripiprazole Sandoz tablets should be swallowed whole and washed down with a glass of water.

Take Aripiprazole Sandoz at about the same time each day.

Unless your doctor gives you other directions, you should take Aripiprazole Sandoz only once a day.

Taking the medicine at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter whether you take Aripiprazole Sandoz with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. Improvement in symptoms may take several days to some weeks to occur. It is important to keep taking your medicine even if you feel well.

If you forget to take your dose

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and

take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much

Immediately telephone your doctor or the Poisons Information Centre (telephone 131126) for advice or go to the Accident Emergency Centre at your nearest hospital, if you or anyone else may have taken too much Aripiprazole Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Aripiprazole Sandoz

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Aripiprazole Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking Aripiprazole Sandoz, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Aripiprazole Sandoz to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give Aripiprazole Sandoz to anyone else, even if they have the same condition as you.

Do not stop taking your medicine, or lower the dosage without checking with your doctor.

If you stop taking Aripiprazole Sandoz suddenly your condition may worsen or your chance of getting an unwanted side effect may increase.

Do not take more of this medicine and do not take it more often than your doctor has ordered.

Things to be careful of

Be careful driving or operating machinery until you know how Aripiprazole Sandoz affects you.

This medicine may cause some people to become drowsy or less alert than they are normally or cause light-headedness, dizziness or tiredness. Make sure that you know how you react to Aripiprazole Sandoz before you do anything that could be dangerous if you are dizzy or light headed or not alert. If this occurs do not undertake the activity.

If you feel light-headed, dizzy or faint, when getting out of bed or standing up, get up slowly.

Be careful when drinking alcohol while you are taking this medicine.

Your doctor may suggest you avoid alcohol while you are being treated with Aripiprazole Sandoz.

Make sure you keep cool in hot weather and keep warm in cool weather.

This medicine may affect the way your body reacts to temperature changes. It may prevent sweating, even during heatwaves. You may feel dizzy or faint if you are too hot. To stay cool in hot weather, try to do the following:

- wear light clothing

- spend time in air-conditioned environments (or keep windows open and use electric fans)
- drink plenty of water
- take cool baths or showers and avoid hot baths and saunas
- try to restrict exercise or heavy work to cool parts of the day.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Aripiprazole Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Aripiprazole Sandoz is generally well-tolerated and the side effects are often hard to distinguish from disease symptoms.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- indigestion
- nausea
- vomiting
- insomnia
- constipation
- light-headedness
- drowsiness
- agitation
- anxiety
- inability to sit or stand still; restless movement of the arms and legs such as tapping, marching in places, rocking, crossing and uncrossing the legs.

These are the more common side effects of Aripiprazole Sandoz.

Tell your doctor if you notice any of the following:

- feeling dizzy especially when getting up from a lying or sitting position
- altered or increased sexual interest

These side effects are uncommon.

- high blood sugar (excessive thirst, hunger and weakness) or the onset or worsening of diabetes

This side effect is rare:

- weight gain,
- weight loss
- loss of appetite
- excessive sweating
- drowsiness
- high blood pressure
- chest pain
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- speech disorder
- urinary incontinence
- difficulty swallowing
- hiccups

These side effects are very rare.

Tell your doctor if you have obsessive (recurring) thoughts or behaviours or trouble controlling impulsive urges or while taking Aripiprazole Sandoz.

Obsessive compulsive behaviours (feeling the need to check things repeatedly or having certain thoughts repeatedly), gambling urges, sexual urges, compulsive spending, binge or compulsive eating and other urges have occurred in some patients.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- seizure, fits or convulsions
- fainting
- abnormal movements of the tongue, or other uncontrolled movements of the tongue,

mouth, cheeks, or jaw which may progress to the arms and legs

- sudden increase in body temperature, sweating, fast heart beat, muscle stiffness, high blood pressure and convulsions
- rash
- allergic reaction (rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body)
- muscle pain, muscle weakness or muscle stiffness
- inflammation of the pancreas, severe upper stomach pain often with nausea and vomiting
- disorder of body temperature regulation resulting in low body temperature or high body temperature
- painful irreversible erection
- difficulty in passing urine
- yellowing of the skin and/or eyes, also called jaundice with or without nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching and dark coloured urine
- serious lung infection with fever, chills, shortness of breath, cough, chest pain and blood streaked phlegm
- thoughts or talk about death or suicide; thoughts or talk about self-harm or doing harm to others; any recent attempts at self-harm; an increase in aggressive behaviour, irritability or agitation. If you or someone you know is showing these signs contact your doctor or a mental health advisor right away or go to the nearest hospital for treatment.

These are very serious side effects.

You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

Also, while taking Aripiprazole Sandoz, some elderly patients with dementia have suffered serious side effects such as a "mini" stroke, stroke, pneumonia or heart problems. These serious side effects can be life threatening.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some patients.

After using Aripiprazole Sandoz

Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in a cool place where the temperature stays below 30°C.

Do not store Aripiprazole Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any leftover medicine.

Be sure that any discarded medicine is out of the reach of children.

Product description

What Aripiprazole Sandoz looks like

Aripiprazole Sandoz 5 mg tablets are blue, mottled, round shaped tablets, debossed with 'SZ' on one side and '444' on the other side.

Aripiprazole Sandoz 10 mg tablets are pink, mottled, round shaped tablets, debossed with 'SZ' on one side and '446' on the other side.

Aripiprazole Sandoz 15 mg tablets are yellow, mottled, round shaped tablets, debossed with 'SZ' on one side and '447' on the other side.

Aripiprazole Sandoz 20 mg tablets are white, round shaped tablets, debossed with 'SZ' on one side and '448' on the other side.

Aripiprazole Sandoz 30 mg tablets are pink, mottled, round shaped tablets, debossed with 'SZ' on one side and '449' on the other side.

Available in blisters of 30 tablets.

Not all strengths or presentations may be marketed in Australia.

Ingredients

Active Ingredient

- Each Aripiprazole Sandoz 5 mg tablet contains 5 mg aripiprazole
- Each Aripiprazole Sandoz 10 mg tablet contains 10 mg aripiprazole
- Each Aripiprazole Sandoz 15 mg tablet contains 15 mg aripiprazole
- Each Aripiprazole Sandoz 20 mg tablet contains 20 mg aripiprazole
- Each Aripiprazole Sandoz 30 mg tablet contains 30 mg aripiprazole.

Inactive Ingredients

- lactose monohydrate
- maize starch
- microcrystalline cellulose
- hypromellose
- magnesium stearate.

The following colorants are also present in the tablets:

Aripiprazole Sandoz 5 mg tablets – indigo carmine aluminium lake

Aripiprazole Sandoz 10 mg tablets - red iron oxide

Aripiprazole Sandoz 15 mg tablets - yellow iron oxide

Aripiprazole Sandoz 20 mg tablets - no colourants

Aripiprazole Sandoz 30 mg tablets - red iron oxide.

This medicine does not contain gluten, tartrazine or any other azo dyes.

This medicine contains sugars as lactose.

Supplier

Aripiprazole Sandoz is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park NSW 2113
Tel: 1800 726 369

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Australian Register Numbers

Aripiprazole Sandoz 5 mg tablets
AUST R 158282

Aripiprazole Sandoz 10 mg tablets
AUST R 158283

Aripiprazole Sandoz 15 mg tablets
AUST R 158281

Aripiprazole Sandoz 20 mg tablets
AUST R 158285

Aripiprazole Sandoz 30 mg tablets
AUST R 158274