

ABYRAZ

aripiprazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ABYRAZ. 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 risks of you taking ABYRAZ against the benefits they expect it will 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 need to read it again.

What ABYRAZ is used for

ABYRAZ contains the active ingredient aripiprazole (ari-pip-rah-zol).

ABYRAZ belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

ABYRAZ is used to treat the symptoms of schizophrenia.

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

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.

ABYRAZ 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 ABYRAZ

When you must not take it

Do not take ABYRAZ if you have an allergy to:

- any medicine containing aripiprazole
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

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

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.

Before you start to take it

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 of the following medical conditions:

- use dot points to list relevant conditions as per PI

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

Your doctor can discuss with you the risks and benefits involved.

ABYRAZ is not recommended for use during pregnancy. If you need to take ABYRAZ during your pregnancy, your doctor will discuss with you the benefits and risks of taking this medicine. Babies exposed to antipsychotics (including aripiprazole) 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 if you are breast-feeding or plan to breast-feed.

It is recommended that you do not breast feed while taking ABYRAZ as it may pass into the breast milk and therefore there is a possibility that the breast-fed baby may be affected.

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 heartbeat, 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 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
- lactose intolerance

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.

If you have not told your doctor about any of the above, tell them before you start taking ABYRAZ.

Taking other medicines

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

Some medicines and ABYRAZ 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 (Neoral®; Sandimmun®)
- a medicine called cimetidine (Magicul)

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

Eating grapefruit or drinking grapefruit juice may affect how ABYRAZ works.

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

How to take ABYRAZ

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 on the pack, ask your doctor or pharmacist for help.

How much to take

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

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

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

Taking it 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 if you take this medicine 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 unless your doctor tells you to.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ABYRAZ. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using ABYRAZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ABYRAZ.

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.

If you become pregnant while taking this medicine, 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 ABYRAZ to treat any other complaints unless your doctor tells you to.

Do not give your medicine 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 it suddenly, your condition may worsen.

Things to be careful of

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

ABYRAZ may cause some people to become drowsy or less alert than they are normally or cause light-headedness, dizziness or tiredness. If this occurs do not undertake the activity.

If ABYRAZ makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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

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

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

ABYRAZ 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 ABYRAZ.

Like other medicines, ABYRAZ may cause some unwanted side effects. These are likely to vary from patient to patient. ABYRAZ is generally well-tolerated and the side effects are often hard to distinguish from disease symptoms. It is important to tell your doctor as soon as possible about unwanted side effects.

You may need medical attention if you get some of the side effects.

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
- constipation
- insomnia
- drowsiness
- light-headedness
- drowsiness
- anxiety
- agitation
- 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

The above list includes the more common side effects of your medicine.

The following are very rare side effects:

- weight gain
- weight loss
- loss of appetite
- excessive sweating

Tell your doctor as soon as possible if you notice any of the following:

- feeling dizzy, especially when getting up from a lying or sitting position
- chest pain
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- signs of high blood sugar (e.g. excessive thirst, increased appetite with weight loss, feeling tired, weakness and passing lots of urine) or the onset or worsening of diabetes
- difficulty in speaking or slurred speech
- urinary incontinence
- difficulty swallowing

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 heartbeat, muscle stiffness, high blood pressure and convulsions
- sudden drop in body temperature
- rash
- allergic reaction
- muscle pain, muscle weakness or muscle stiffness
- severe upper stomach pain often with nausea and vomiting (may be a sign of inflammation of the pancreas)
- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some people.

While taking ABYRAZ, 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.

After using ABYRAZ

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ABYRAZ 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 medicine that is left over.

Product description

What it looks like

ABYRAZ 10 mg tablets: pink, oblong, biconvex tablets. The tablets are debossed with "ARZ" and "10" on one side.

ABYRAZ 15 mg tablets: yellow, round, biconvex tablets. The tablets are debossed with "ARZ" and "15" on one side.

ABYRAZ 20 mg tablets: white, round, biconvex tablets. The tablets are debossed with "ARZ" and "20" on one side.

ABYRAZ 30 mg tablets: pink, round, biconvex tablets. The tablets are debossed with "ARZ" and "30" on one side.

ABYRAZ tablets are packed in a blister pack inside a carton. Each carton contains 30 tablets.

Ingredients

ABYRAZ 10 mg tablets contains 10 mg of aripiprazole as the active ingredient.

ABYRAZ 15 mg tablets contains 15 mg of aripiprazole as the active ingredient.

ABYRAZ 20 mg tablets contains 20 mg of aripiprazole as the active ingredient.

ABYRAZ 30 mg tablets contains 30 mg of aripiprazole as the active ingredient.

The other ingredients in the medicine are:

- sodium starch glycollate Type A
- microcrystalline cellulose
- lactose monohydrate
- hypolose
- magnesium stearate

The 10 mg and 30 mg tablets also contain iron oxide red.

The 15 mg tablets also contain iron oxide yellow.

Manufacturer

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.mylan.com.au

10 mg tablets: AUST R 159503

15 mg tablets: AUST R 159506

20 mg tablets: AUST R 159505

30 mg tablets: AUST R 159504

This leaflet was prepared in September 2017.

ABYRAZ_cmi\0917\00