

MYCOPHENOLIC ACID ARX

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using MYCOPHENOLIC ACID ARX?

MYCOPHENOLIC ACID ARX contains the active ingredient mycophenolic acid (as sodium). MYCOPHENOLIC ACID ARX is used for people who have had a kidney transplant, to prevent the body from rejecting the new kidney.

For more information, see Section [1. Why am I using MYCOPHENOLIC ACID ARX?](#) in the full CMI.

2. What should I know before I use MYCOPHENOLIC ACID ARX?

Do not use if you have ever had an allergic reaction to MYCOPHENOLIC ACID ARX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use MYCOPHENOLIC ACID ARX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MYCOPHENOLIC ACID ARX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use MYCOPHENOLIC ACID ARX?

- Keep your tablets in the foil blister pack until it is time to take them. If you take the tablets out of the blister pack, they will not keep well.
- Store the pack in a cool dry place where the temperature stays below 25°C.

More instructions can be found in Section [4. How do I use MYCOPHENOLIC ACID ARX?](#) in the full CMI.

5. What should I know while using MYCOPHENOLIC ACID ARX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using MYCOPHENOLIC ACID ARX.• You must not take this medicine while you are pregnant or breast-feeding. If you become pregnant while taking MYCOPHENOLIC ACID ARX, tell your doctor immediately
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine unless your doctor tells you to.• Do not have any vaccinations without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• MYCOPHENOLIC ACID ARX may cause dizziness in some people.• Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking MYCOPHENOLIC ACID ARX until you know how it affects you.
Drinking alcohol	<ul style="list-style-type: none">• Alcohol may have some effects while taking MYCOPHENOLIC ACID ARX
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the foil blister pack until it is time to take them. If you take the tablets out of the blister pack, they will not keep well.

For more information, see Section [5. What should I know while using MYCOPHENOLIC ACID ARX?](#) in the full CMI.

6. Are there any side effects?

The common side effects include diarrhea, indigestion, bloating, muscle pain, weakness, pain in joint, pain in stomach.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

MYCOPHENOLIC ACID ARX

Active ingredient(s): *mycophenolic acid (as sodium) enteric coated tablets*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MYCOPHENOLIC ACID ARX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MYCOPHENOLIC ACID ARX.**

Where to find information in this leaflet:

- [1. Why am I using MYCOPHENOLIC ACID ARX?](#)
- [2. What should I know before I use MYCOPHENOLIC ACID ARX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MYCOPHENOLIC ACID ARX?](#)
- [5. What should I know while using MYCOPHENOLIC ACID ARX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MYCOPHENOLIC ACID ARX?

MYCOPHENOLIC ACID ARX contains the active ingredient **mycophenolic acid**. It belongs to a group of medicines called immunosuppressive. These medicines work by stopping your immune system from rejecting the transplanted organ.

MYCOPHENOLIC ACID ARX is used for people who have had a kidney transplant, to prevent the body from rejecting the new kidney.

MYCOPHENOLIC ACID ARX is used for people who have inflammatory kidney disease associated with a chronic autoimmune disorder known as systemic lupus erythematosus (also called lupus or SLE).

MYCOPHENOLIC ACID is used in combination with other medicines.

2. What should I know before I use MYCOPHENOLIC ACID ARX?

Warnings

Do not use MYCOPHENOLIC ACID ARX if:

- you are allergic to mycophenolic acid, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Symptoms of allergic reaction include:
Shortness of breath;
Wheezing or difficulty.

Breathing or faintness;
Swelling of face, lips, tongue, or other parts of the body;
Rash, itching, hives on the skin

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use of MYCOPHENOLIC ACID ARX in pregnancy causes a very high frequency of loss of pregnancy (miscarriage) and of severe birth defects in the unborn baby.

Do not take MYCOPHENOLIC ACID ARX if you are not using effective contraception.

Your doctor should advise you about contraception before you start taking MYCOPHENOLIC ACID ARX. Reliable contraception must be used before starting MYCOPHENOLIC ACID ARX.

MYCOPHENOLIC ACID ARX may reduce blood levels of the hormones in oral contraceptive pills and could theoretically reduce their effectiveness. Use of two methods of contraception is advised. The two methods can be a double barrier method or a barrier method plus a hormonal method. Adequate barrier methods of contraception include diaphragm, condom (by the partner), intrauterine device, sponge, or spermicide.

Do not take MYCOPHENOLIC ACID ARX if you are breastfeeding during treatment with MYCOPHENOLIC ACID ARX. This is because small amounts of the medicine can pass into the mother's milk.

Sexually active men are recommended to use condoms during treatment and for total of 13 weeks after their last dose of Mycophenolate sodium. Condom use applies for both reproductively competent and vasectomized men, because the risks associated with the transfer of seminal fluids also apply to men who have had a vasectomy.

In addition, female partners of male patients are recommended to use highly effective contraception during treatment and for a total of 13 week after the last dose of Mycophenolate sodium.

3. What if I am taking other medicines?

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

Some medicines may interfere with MYCOPHENOLIC ACID ARX. These medicines include:

- antacids that contain magnesium or aluminium hydroxide
- azathioprine, tacrolimus, or any other immunosuppressive medicine
- certain live vaccines
- cholestyramine (used to treat high blood cholesterol levels)
- aciclovir or ganciclovir (used to treat viral infections)
- oral contraceptives. These may not work as well while you are taking MYCOPHENOLIC ACID ARX and you could become pregnant. Talk to your doctor about other birth control methods that can be used while you are taking MYCOPHENOLIC ACID ARX.

You may need to take different amounts of your medicines, or you may need to take different medicines.

Tell your doctor if you have or have had:

- Sunspots or skin cancers
- Low neutrophil (a type of white blood cell) blood count
- Serious problems with your stomach or bowel, such as ulcers or bleeding.
- Lesch-Nyhan or Kelly-Seegmiller syndrome 9a rare hereditary disorder that affects males only and is caused by a deficiency of a specific enzyme).

Your doctor may not want you to take MYCOPHENOLIC ACID ARX or may want to take special precautions if you have any of the above conditions.

If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment and must follow the contraceptive advice given to you by your doctor. Your doctor may request more than one test to ensure you are not pregnant before starting MYCOPHENOLIC ACID ARX.

If you are planning to have a child, your doctor will talk to you about the risks and alternative treatment you can take to prevent rejection of your transplant organ.

Tell your doctor if you are lactose intolerant. MYCOPHENOLIC ACID ARX tablets contain lactose.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MYCOPHENOLIC ACID ARX.

4. How do I use MYCOPHENOLIC ACID ARX?

How much to take / use

- Do not exceed the recommended dosage. The usual dose is 1,440 mg, take 720 mg twice a day. Your doctor may have prescribed a different dose, particularly for the initial treatment of inflammatory kidney disease.
- Take MYCOPHENOLIC ACID ARX as prescribed by your doctor.
- This will ensure that this medicine will work properly and prevent any unwanted side effects.
- Remove the tablets from the foil blister pack when you are ready to take them.
- Swallow the tablets whole with a full glass of water.
- Do not chew or crush the tablets. Do not take any tablets that are broken or split.
- You may take MYCOPHENOLIC ACID ARX tablets with or without food. It does not matter if you take them after food or on an empty stomach, as long as you take it the same way each day.
- If you take them with food, always take them with food. If you take them without food, always take them without food.

When to take / use MYCOPHENOLIC ACID ARX

- MYCOPHENOLIC ACID ARX should be used twice a day, 12 hours apart if possible. Taking your dose 12 hours apart will have the best effect.
- Take them at about the same time each day. This will help you remember when to take them.

If you have had a renal transplant, your first dose will usually be given within 48 hours after your transplant.

How long to take MYCOPHENOLIC ACID ARX

Keep taking this medicine for as long as your doctor recommends.

It is important to keep taking MYCOPHENOLIC ACID ARX to prevent rejection of your transplanted kidney.

If you forget to use MYCOPHENOLIC ACID ARX

MYCOPHENOLIC ACID ARX should be used regularly at the same time each day.

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 you missed.

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

If you use too much MYCOPHENOLIC ACID ARX

If you think that you have used too much MYCOPHENOLIC ACID ARX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MYCOPHENOLIC ACID ARX?

Things you should do

Call your doctor straight away if you:

- Make sure that you keep all of your doctor's appointments and have any tests done that are ordered by your doctor.
- Your doctor may ask you to have blood tests from time to time to check your progress and prevent side effects.
- You must not take this medicine while you are pregnant or breast-feeding. If you become pregnant while taking MYCOPHENOLIC ACID ARX, tell your doctor immediately.
- Your doctor will discuss the potential risks of taking MYCOPHENOLIC ACID ARX during pregnancy such as miscarriage and a higher risk of birth defects.
- If you are a woman of child-bearing age, you must use effective contraception measures before you take MYCOPHENOLIC ACID ARX, while you are taking MYCOPHENOLIC ACID ARX, and for 6 weeks after you stop taking MYCOPHENOLIC ACID ARX. If you are taking oral contraceptives, you must also use another form of birth control.
- If you are a sexually active man, you should use condoms during treatment with MYCOPHENOLIC ACID ARX and for 13 weeks after stopping treatment even if you have had a vasectomy. Your partner should also use effective contraception during your treatment and for 13 weeks after you have stopped MYCOPHENOLIC ACID ARX.
- Contact your doctor as soon as possible if you think your contraception may not have been effective or if you have forgotten to take your contraceptive pill.
- Tell your doctor immediately if your partner becomes pregnant while you are taking MYCOPHENOLIC ACID ARX.
- Do not breast-feed during treatment with MYCOPHENOLIC ACID ARX and for 6 weeks after you have stopped taking MYCOPHENOLIC ACID ARX.
- If you develop lumps anywhere in your body, or develop any moles, or you notice changes in existing moles, tell your doctor.
- This may be an early sign of cancer. Immunosuppressant medicines, including MYCOPHENOLIC ACID ARX, may increase the risk of developing certain cancers, including skin cancer and lymphoma (cancer of the lymphatic system).
- Take special care during exposure to sunlight. If you go out in the sun, limit your exposure to sunlight and

UV light by wearing a hat, protective clothing, and sunscreen with a high protection factor.

- This will help to prevent the development of skin cancer.
- Take special care of your teeth and gums. People taking immunosuppressant medicines are at a greater risk of getting infections.
- Taking good care of your teeth and gums will help to prevent dental and mouth infections.
- If you experience any symptoms of infection (e.g., fever, sore throat), unexpected bruising and/or bleeding you should inform your doctor immediately.
- If you have already had hepatitis B or C, MYCOPHENOLIC ACID ARX may increase the risk of these diseases re-appearing.
- Your doctor may perform blood analysis and check for symptoms of these diseases. If you experience any symptoms (yellow skin and eyes, nausea, loss of appetite, dark urine) you should inform your doctor immediately.
- You must not donate blood during treatment with MYCOPHENOLIC ACID ARX and for at least 6 weeks after stopping treatment.
- Men must not donate semen during treatment with MYCOPHENOLIC ACID ARX and for at least 90 days after stopping treatment.
- If you are about to be started on any new medicine remind your doctor or pharmacist that you are taking MYCOPHENOLIC ACID ARX.
- Remind any doctor, dentist, or pharmacist you visit that you are using MYCOPHENOLIC ACID ARX.

Things you should not do

- Do not stop taking this medicine unless your doctor tells you to.
- Do not have any vaccinations without first checking with your doctor.
- Some vaccines may be less effective, or they may cause unwanted side effects while you are taking MYCOPHENOLIC ACID ARX.
- Do not give this medicine to anyone else even if their condition seems like yours.
- Do not take it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MYCOPHENOLIC ACID ARX affects you.

MYCOPHENOLIC ACID ARX may cause dizziness in some people.

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking MYCOPHENOLIC ACID ARX until you know how it affects you.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may affect the effects of MYCOPHENOLIC ACID ARX.

Looking after your medicine

- Keep your tablets in the foil blister pack until it is time to take them. If you take the tablets out of the blister pack, they will not keep well.
- Store the pack in a cool dry place where the temperature stays below 25°C.
- Always keep the tablets away from direct sunlight and keep the tablets away from moisture.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

When to discard your medicine (as relevant)

If your doctor tells you to stop taking MYCOPHENOLIC ACID ARX or it has passed its expiry date, ask your pharmacist what to do with any medicine you have left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Diarrhoea • Constipation • Indigestion • Flatulence • Loose stools • Nausea (feeling sick), or vomiting 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • Pain in the stomach • Pain in the joints • Weakness • Muscle pain • Feeling bloated or tenderness in the abdomen • Headache • Dizziness • Unusual bleeding or bruising (signs of low level of blood platelets) • Cough • Anxiety • Fever 9temperature above 37°C • Tiredness 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Symptoms of infection including fever, chills, sweating, feelings of tiredness, drowsiness, or lack of energy. • vision changes, loss of coordination, clumsiness, memory loss, difficulty speaking or understanding what others say, and muscle weakness. These can be the signs of an infection of the brain called progressive multifocal leukoencephalopathy. • signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing or you feel congested. • enlarged glands, a new lump or mole on your skin, or changes to existing moles, anywhere 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>on the body. A very small number of MYCOPHENOLIC ACID ARX patients have developed cancer of the skin or lymph nodes. Lymph nodes are the bean-shaped organs found in the underarm, groin, neck, chest and abdomen that act as filters for the lymph fluid as it circulates through the body.</p> <ul style="list-style-type: none"> • any symptoms of anemia (decrease in red blood cells), such as unusual tiredness, headache, shortness of breath at rest or with exercise, dizziness, chest pain, looking pale. • signs of peripheral oedema such as swollen hands, ankles or feet. • signs of severe high blood pressure such as headache, dizziness, possibly with nausea. • signs of high levels of potassium in the blood (hyperkalaemia) such as muscle spasms, abnormal heart rhythm. • signs of interstitial lung disease including fatal pulmonary fibrosis) such as cough, difficulty breathing, painful breathing • General disorders and administration site conditions: de novo purine synthesis inhibitors-associated acute inflammatory syndrome. 	

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What MYCOPHENOLIC ACID ARX contains

Active ingredient (main ingredient)	Mycophenolic acid (as sodium) 180mg or 360mg
Other ingredients (inactive ingredients)	Microcrystalline cellulose Croscarmellose sodium Povidone Croscarmellose sodium Purified talc Colloidal anhydrous silica Magnesium stearate Isopropyl alcohol Purified water PI: Opacode Black S-1-1782. PI: Acryl-Eze Green 930510003 aqueous acrylic enteric system
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What MYCOPHENOLIC ACID ARX looks like

MYCOPHENOLIC ACID ARX tablets 180 mg are lime green, round shaped, biconvex bevelled edged enteric-coated tablets imprinted with M1 on one side with black ink and plain on the other side (AUST R 338491).

Available in 20, 50, 100 and 120 tablets pack sizes

MYCOPHENOLIC ACID ARX tablets 360 mg are peach, oblong shaped, biconvex enteric-coated tablets imprinted with M2 on one side with black ink and plain on the other side (AUST R 338496).

Available in 50, 100 and 120 tablets pack sizes

* Not all strengths or pack sizes may be available.

Who distributes MYCOPHENOLIC ACID ARX

Arrortex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

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