

ARX-Mycophenolate

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 ARX-Mycophenolate?

ARX-Mycophenolate contains the active ingredient mycophenolate mofetil. ARX-Mycophenolate is used to prevent the rejection of a transplanted organ. For more information, see Section [1. Why am I taking ARX-Mycophenolate?](#) in the full CMI.

2. What should I know before I take ARX-Mycophenolate?

Do not use if you have ever had an allergic reaction to mycophenolate mofetil, a related medicine called mycophenolic acid, or any of the ingredients listed at the end of the CMI. Do not use if you are pregnant or breast feeding, or if you are a woman who could become pregnant and you are not using two reliable forms of contraception.

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 take ARX-Mycophenolate?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARX-Mycophenolate 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 take ARX-Mycophenolate?

- Your doctor will tell you how many ARX-Mycophenolate tablets to take each day.

More instructions can be found in Section [4. How do I take ARX-Mycophenolate?](#) in the full CMI.

5. What should I know while taking ARX-Mycophenolate?

Things you should do	<ul style="list-style-type: none">Tell any doctor, surgeon, anaesthetist, dentist or pharmacist that is treating you that you are using ARX-Mycophenolate.Wear protective clothing and broad-spectrum sunscreen when outdoors.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine without first checking with your doctor.Do not take any other medicines - whether they require a prescription or not - without first telling your doctor or consulting with a pharmacist.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how ARX-Mycophenolate affects you, or if you experience somnolence (drowsiness) (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).
Looking after your medicine	<ul style="list-style-type: none">Keep ARX-Mycophenolate tablets in a cool dry place where the temperature stays below 25 °C.

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

6. Are there any side effects?

More common side effects include diarrhoea, constipation, nausea, vomiting, indigestion, pain in the stomach, chest or back, headache, and urinary infection. Less common but possibly serious side effects include infections, bruising, anaemia, swelling of the hands, ankles or lymph nodes (glands), chronic cough with blood and allergic reactions such as chest tightness, wheezing, difficulty breathing, severe dizziness or light-headedness, swelling of the face, lips, tongue, throat with difficulty breathing, skin rash, itching or hives (raised red patches of skin that are often very itchy).

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.

ARX-Mycophenolate

Active ingredient: *Mycophenolate mofetil*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking ARX-Mycophenolate?

ARX-Mycophenolate contains the active ingredient mycophenolate mofetil.

ARX-Mycophenolate belongs to a group of medicines called immunosuppressants. Immunosuppressants are used to prevent the rejection of a transplanted organ and work by stopping your immune system from reacting to the transplanted organ.

There are many different types of medicines used to prevent rejection of a transplanted organ.

ARX-Mycophenolate may be taken together with other medicines known as ciclosporin and corticosteroids.

2. What should I know before I take ARX-Mycophenolate?

Warnings

Do not take ARX-Mycophenolate if:

- you are allergic to mycophenolate mofetil, a related medicine called mycophenolic acid, or any of the ingredients listed at the end of this leaflet.** Some of the symptoms of a serious allergic reaction may include:
 - chest tightness, wheezing or difficulty breathing
 - severe dizziness or light headedness
 - swelling of the face, lips, tongue, throat or other parts of the body with difficulty breathing
 - skin rash, itching or hives (raised red patches of skin that are often very itchy)
- you are pregnant**
 - ARX-Mycophenolate is harmful to an unborn baby when taken by a pregnant woman.
 - There have been cases of miscarriage and severe birth defects reported when patients have taken ARX-Mycophenolate during pregnancy.
 - You must tell your doctor if you are pregnant or plan to become pregnant.
- you are breast feeding**
 - ARX-Mycophenolate can pass into human breast milk and could cause serious side effects in your baby if you breastfeed.

- you are a woman who could become pregnant and you are not using two reliable forms of contraception**
 - You must use two reliable forms of contraception at the same time before beginning ARX-Mycophenolate therapy, during therapy, and for at least six weeks after stopping ARX-Mycophenolate, unless you are not sexually active.
- the package is torn or shows signs of tampering**
- the expiry date (EXP) printed on the pack has passed.**
 - If you take this medicine after the expiry date has passed it may not work as well.

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

Check with your doctor if you:

- are a sexually active man**
 - you are recommended to use condoms during treatment and for 90 days after stopping treatment, even if you have had a vasectomy.
 - your female partner(s) are recommended to use reliable contraception while you are being treated with ARX-Mycophenolate and for 90 days after you have stopped receiving ARX-Mycophenolate
 - you should not donate semen while you are being treated with ARX-Mycophenolate and for 90 days after you have stopped receiving ARX-Mycophenolate
- have any other health problems, especially the following:**
 - a history of sun spots or skin cancers
 - a history of low blood counts of neutrophils (a type of white blood cell)
 - a history of serious stomach or bowel problems (such as ulceration or bleeding)
 - rare diseases due to a deficiency of the HGPRT enzyme such as Lesch-Nyhan or Kelley-Seegmiller syndrome
 - kidney disease
 - have allergies to any other medicines, foods, preservatives or dyes.

You should not donate blood while you are being treated with ARX-Mycophenolate and for at least 6 weeks after you stop receiving ARX-Mycophenolate.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for 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. If you are a woman of child bearing potential, you must have two negative pregnancy tests 8-10 days apart just prior to starting treatment with ARX-Mycophenolate.

Repeat pregnancy tests will be performed during routine follow-up visits with your doctor.

Talk to your doctor if you are breast feeding or intend to breast feed.

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 ARX-Mycophenolate and affect how it works. These include:

- azathioprine, tacrolimus and sirolimus – medicines used to suppress the immune system which can be used to prevent organ rejection after a transplant
- acyclovir, ganciclovir, valaciclovir or valganciclovir used to treat certain viral infections
- isavuconazole - used to treat fungal infections
- antacids - used to treat heartburn and indigestion
- cholestyramine - used to treat high cholesterol
- ciprofloxacin, amoxicillin plus clavulanic acid, norfloxacin plus metronidazole, and rifampicin and other medicines used to treat infections
- iron supplements - used to treat low iron levels in the blood
- certain vaccines, (especially live vaccines) - medicines that work by causing your body to produce its own protection against an infectious disease
- proton-pump inhibitors such as lansoprazole and pantoprazole - used to treat indigestion and stomach ulcers
- telmisartan – used to treat high blood pressure
- calcium-free phosphate binders (such as sevelamer) - used to treat high phosphate levels in the blood

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

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

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

4. How do I take ARX-Mycophenolate?

How much to take

Take ARX-Mycophenolate exactly as your doctor has prescribed.

Your doctor will tell you how many ARX-Mycophenolate tablets to take each day.

The dose to prevent organ rejection is usually 1 g to 1.5 g in the morning and 1 g to 1.5 g at night (2 g to 3 g per day) depending on which organ has been transplanted.

Children

For renal transplant only.

For children 2 to 18 years of age, the dose to prevent organ rejection is dependent on the child's height and weight. The maximum dose is usually 1 g in the morning and 1 g at night (2 g daily).

How to take it

Swallow the tablets whole with a full glass of water.

Do not crush tablets. If a tablet breaks accidentally, wash any powder off your skin with soap and water.

When to take ARX-Mycophenolate

It is best to take doses of ARX-Mycophenolate tablets approximately 12 hours apart.

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

How long to take ARX-Mycophenolate

ARX-Mycophenolate should be taken every day. It is important to keep taking ARX-Mycophenolate to ensure your new transplant keeps working properly.

Continue taking ARX-Mycophenolate for as long as your doctor tells you.

If you forget to take ARX-Mycophenolate tablets

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 it as you would normally.

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

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 ARX-Mycophenolate

If you think that you have taken too much ARX-Mycophenolate, 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 taking ARX-Mycophenolate?

Things you should do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking ARX-Mycophenolate.

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.

Tell your doctor if you become pregnant while taking ARX-Mycophenolate. If you are a woman of child bearing potential, you must use two reliable forms of contraception at the same time before beginning ARX-Mycophenolate therapy, during therapy and for at least six weeks after stopping ARX-Mycophenolate, unless you are not sexually active.

If you are a sexually active male, you are recommended to use condoms during treatment and for 90 days after stopping treatment, even if you have had a vasectomy. Your female partner(s) are recommended to use reliable contraception while you are being treated with ARX-Mycophenolate and for 90 days after you have stopped receiving ARX-Mycophenolate.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel your medicine is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked. Your doctor will need to give you regular blood tests.

Wear protective clothing and broad-spectrum sunscreen when outdoors. Medicines that prevent the rejection of transplanted organs can increase the risk of skin cancers.

Things you should not do

Do not stop taking ARX-Mycophenolate or change the dose without first checking with your doctor.

Do not use ARX-Mycophenolate 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 let yourself run out of medicine over the weekend or on holidays.

Do not crush ARX-Mycophenolate tablets.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Driving or using machines

Be careful driving or operating machinery until you know how ARX-Mycophenolate affects you or if you experience somnolence (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).

ARX-Mycophenolate may affect your ability to drive a car or operate machinery.

Looking after your medicine

Do not store ARX-Mycophenolate 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.

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.

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

When to discard your medicine

If your doctor tells you to stop taking ARX-Mycophenolate, or the expiry date has passed, 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.

To stop you rejecting your organ, transplant medications reduce your body's own defence mechanisms. This means your body will not be as good at fighting infection. People receiving ARX-Mycophenolate therefore develop more infections than usual and this could increase the severity of the infections.

Patients who receive immunosuppressant medicines may also have a small increase in their risk of developing some types of cancer. You should discuss this with your doctor.

If you are over 65 years of age you may have an increased chance of side effects occurring due to immunosuppression.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • diarrhoea, constipation, nausea (feeling sick), vomiting or indigestion • stomach, chest or back pain • headache • urinary infections • acne • hair loss or itchy skin 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • signs of other infections, e.g. fevers, chills, sore throat, ulcers of the mouth, abdominal pain or bloody stools. • unexpected bruising or bleeding • signs of anaemia such as excessive tiredness, dizziness or looking pale • swelling of the hands, ankles or feet, lymph nodes (glands) • inability to sleep (insomnia) • signs of allergic reaction (chest tightness, wheezing or difficulty breathing, severe dizziness or light-headedness, swelling of the face, lips, tongue, throat, or other parts of the body with difficulty breathing, skin rash, itching or hives appearing as raised red patches of skin that are very itchy) • breathing difficulties, pain in the chest, chronic cough with blood. 	<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>

The above list includes serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Other side effects may occur in some people and there may be some others that are not yet known.

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.

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.

ARX-Mycophenolate 500 mg tablets come in packs of 50 tablets.

Active ingredient (main ingredient)	Mycophenolate mofetil
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Microcrystalline cellulose• Croscarmellose sodium• Povidone• hyprollose• Magnesium stearate• Purified talc OPADRY complete film coating system 03B50110 PURPLE
Potential allergens	ARX-Mycophenolate tablets are gluten and lactose free.

ARX-Mycophenolate tablets are purple coloured, capsule shaped, biconvex, film coated tablets debossed 'AHI' on one side and '500' on other side. AUST R 235572.

Sponsor

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