

MYCOTEX

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 MYCOTEX?

MYCOTEX contains the active ingredient mycophenolate sodium. MYCOTEX is used in adult patients: 1) to prevent the body from rejecting a transplanted kidney; 2) It is also used to treat inflammatory kidney disease associated with chronic autoimmune disorder known as systemic lupus erythematosus (also called lupus or SLE). MYCOTEX is used in combination with other medicines. For more information, see Section [1. Why am I using MYCOTEX?](#) in the full CMI.

2. What should I know before I use MYCOTEX?

Do not use if you have ever had an allergic reaction to mycophenolate sodium 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 MYCOTEX ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MYCOTEX 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 MYCOTEX?

- The usual dose is 1,440 mg, taken as 720 mg twice a day.
- Doctor may prescribe a different dose, particularly for the initial treatment of inflammatory kidney disease.

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

5. What should I know while using MYCOTEX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using MYCOTEX.• Ensure you keep all your doctor's appointments and have any tests (including blood tests) ordered by your doctor.• Use effective contraception measures while you are taking MYCOTEX.• Tell your doctor immediately, if you have COVID-19 or if you become pregnant while taking MYCOTEX.• Tell your doctor immediately, if you develop lumps or notice any moles anywhere in your body or if you notice changes in existing moles – this may be a sign of cancer.
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 have any vaccinations without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking MYCOTEX 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	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Store in original container to protect from moisture.• Keep your tablets in the foil blister pack until it is time to take them.

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

6. Are there any side effects?

Less serious side effects: diarrhoea, constipation, indigestion, flatulence, loose stools, nausea (feeling sick), or vomiting, pain in the stomach, pain or swelling in the joints, weakness.

Serious side effects: symptoms of infection including fever, chills, sweating, feelings of tiredness, drowsiness, or lack of energy. 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.

MYCOTEX

Active ingredient(s): *mycophenolate sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MYCOTEX. **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 MYCOTEX.**

Where to find information in this leaflet:

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

1. What am I using MYCOTEX?

MYCOTEX contains the active ingredient, **mycophenolate sodium**.

MYCOTEX belongs to a group of medicines called immunosuppressives. These medicines work by stopping your immune system from rejecting the transplanted organ.

MYCOTEX is used for people who have had a kidney transplant, to prevent the body from rejecting the new kidney. It is also used for people who have inflammatory kidney disease associated with a chronic autoimmune disorder known as systemic lupus erythematosus (also called lupus or SLE). MYCOTEX is used in combination with other medicines.

2. What should I know before I use MYCOTEX?

Warnings

Do not use MYCOTEX if:

- you are allergic to mycophenolate sodium (the active ingredient in MYCOTEX), or any of the ingredients listed at the end of this leaflet.
- you are pregnant, think you may be pregnant, or intend to become pregnant.
- you are not using effective contraception.
- you are breastfeeding.
- the package is torn or shows signs of tampering
- the expiry date printed on the pack has passed

Always check the ingredients to make sure you can use this medicine.

Check with 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 Kelley-Seegmiller syndrome (a 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 MYCOTEX or may want to take precautions if you have any of the above conditions.

- **plan to have vaccinations.**
- **are lactose intolerant as MYCOTEX tablets contain lactose.**
- **are allergic to any other medicines, foods, dyes or preservatives.**

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. You must not take MYCOTEX if you are pregnant. 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 MYCOTEX.

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

- **Talk to your doctor if you are breastfeeding or intend to breastfeed.** You must not breastfeed during treatment with MYCOTEX. This is because small amounts of the medicine can pass into the mother's milk.

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?](#)

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 a pharmacy, supermarket or health food shop.

Some medicines may interfere with MYCOTEX.

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 MYCOTEX and you could become pregnant. Talk to your doctor about other birth control methods that can be used while you are taking MYCOTEX.

You may need to take 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 MYCOTEX.

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

4. How do I use MYCOTEX?

How much to take

- The usual dose is 1,440 mg, taken as 720 mg twice a day. Your doctor may have prescribed a different dose, particularly for the initial treatment of inflammatory kidney disease.
- Take MYCOTEX exactly as your doctor has prescribed.

This will ensure that this medicine will work properly and prevent any unwanted side effects.

Follow the instructions provided and use MYCOTEX until your doctor tells you to stop.

When to take MYCOTEX

- MYCOTEX should be taken twice a day, 12 hours apart if possible. Taking your doses 12 hours apart will have the best effect.
- If you have had a renal transplant, your first dose will usually be given within 48 hours after your transplant.

How to take MYCOTEX

- 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 MYCOTEX with or without food. It does not matter if you take MYCOTEX after food or on an empty stomach, if you take it the same way each day.
- If you take it with food, always take it with food.
- If you take it without food, always take it without food.

If you forget to use MYCOTEX

MYCOTEX should be used regularly at the same time each day. This will also help you remember when to take it.

If it is almost time for your next dose, skip the dose you missed and take the 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. This may increase your chance of you getting an unwanted side effect.

If you miss more than one dose, contact your doctor as soon as possible.

If you take too much MYCOTEX

If you think that you have used too much MYCOTEX, 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 MYCOTEX?

Things you should do

- Make sure to keep all of your doctor's appointments and have any tests done that are ordered by your doctor.
- If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist you visit that you are using MYCOTEX.
- If you are a woman of child-bearing age, you must use effective contraception measures before you take MYCOTEX, while you are taking MYCOTEX, and for 6 weeks after you stop taking MYCOTEX. 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 MYCOTEX 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 MYCOTEX.
- 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

Call your doctor straight away if you:

- Have COVID-19. Increased severity of COVID-19 may occur with MYCOTEX.
- are a woman or child-bearing age, taking effective contraception measures and you think your contraception may not have been effective or if you have forgotten to take your contraceptive pill
- are a sexually active man, and your partner becomes pregnant while you are taking MYCOTEX.
- develop lumps anywhere in your body, or develop any moles, or you notice changes in existing moles. This may be an early sign of a cancer. Immunosuppressant medicines, including MYCOTEX, may increase the risk of developing certain cancers,

including skin cancer and lymphoma (cancer of the lymphatic system).

Things you should not do

- Do not stop using this medicine without first checking with your doctor.
- Do not have any vaccinations without first checking with your doctor.
- Do not give MYCOTEX to anyone else even if their condition seems similar to yours.
- Do not donate blood during treatment with MYCOTEX and for at least 6 weeks after stopping treatment.
- Do not breastfeed during treatment with MYCOTEX and for 6 weeks after you have stopped taking MYCOTEX.
- Men must not donate semen during treatment with MYCOTEX and for at least 90 days after stopping treatment.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MYCOTEX affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your tablets in the foil blister pack until it is time to take them.
- Store below 25°C.

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.

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"> • Diarrhea, nausea (feeling sick), constipation, vomiting, loose stools, indigestion, flatulence, stomach pain, feeling bloated, tenderness in the stomach • Headache, dizziness, anxiety • Weakness, muscle pain, pain or swelling in the joints, tiredness • Cough, fever • Unusual bleeding or bruising 	<p>Speak to your doctor if you have any of these less serious side and they worry you:</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Signs of severe allergic reactions including rash, itching, hives on the skin, swelling of the face, lips, tongues or other part of the body, breathlessness or difficulty breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, hypotension with or without mild generalized itching, skin reddening and facial/throat swelling. • Enlarged glands, a new lump or mole on your skin, or changes to existing moles, anywhere on the body. • Vision changes, loss of coordination, clumsiness, memory loss, difficulty speaking or understanding what others say and muscle weakness. • Signs of infection including fever, chills, sweating, tiredness, drowsiness, urinary infections, respiratory tract infections and skin infections 	<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>

<ul style="list-style-type: none"> • Signs of anemia (decrease in red blood cells) including unusual tiredness, headache, shortness of breath, chest pain, looking pale. 	
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Tell your doctor if you notice anything else that is 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 MYCOTEX contains

Active ingredient (main ingredient)	Mycophenolic Acid (as Mycophenolate Sodium USP) 360 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Silicon Dioxide • Povidone • Lactose • Maize starch • Crospovidone • Magnesium Stearate • Hypromellose Phthalate • Triethyl Citrate • OPADRY II complete film coating system 85F540054 PINK • OPACODE monogramming ink S-1-17823 BLACK. • OPADRY II complete film coating system 85F540054 PINK contains polyvinyl alcohol, titanium dioxide, macrogol, talc, iron oxide yellow and iron oxide

	red
	<ul style="list-style-type: none">• OPACODE monogramming ink S-1-17823 BLACK contains shellac, iron oxide black, and propylene glycol

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

What MYCOTEX looks like

MYCOTEX 360 mg are pale orange-red colored, oval shaped, biconvex, film coated tablets imprinted "MA 360" with black ink on one side and plain on other side.

The film-coated tablets are packed in

- Alu-Alu Blister Pack of 50's, 120's Tablets
- HDPE Bottle Pack of 120's Tablets

Who distributes MYCOTEX

Pharmacor Pty Ltd.
CHATSWOOD, NSW 2067,
Australia

Australian Registration Numbers:

360 mg enteric-coated tablet bottle pack: 391535

360 mg enteric-coated tablet blister pack: 391538

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