

## 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 enteric-coated tablets contains the active ingredient Mycophenolic acid. MYCOTEX is used for the prophylaxis of acute transplant rejection in adult patients receiving allogeneic renal transplants. MYCOTEX is indicated for induction and maintenance treatment of adult patients with WHO Class III, IV or V lupus nephritis. 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 MYCOTEX 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?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using MYCOTEX.</li><li>• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MYCOPHENOLIC ACID.</li><li>• Do not take MYCOTEX if you are pregnant, think you may be pregnant, or intend to become pregnant.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give this medicine to anyone else, even if their condition seems similar to yours.</li><li>• Do not use it to treat any other complaints unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• 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.</li><li>• This medicine is not expected to affect your ability to drive a car or operate machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25°C. Store in original container to protect from moisture.</li><li>• Keep out of reach of children.</li></ul>

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.

**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 MYCOTEX is used for?](#)
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 MYCOTEX is used for?**

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.

**How MYCOTEX works**

MYCOTEX contains the active ingredient, mycophenolic acid. It belongs to a group of medicines called immunosuppressives. These medicines work by stopping your immune system from rejecting the transplanted organ.

**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.

MYCOTEX is only available with a doctor's prescription. It is not addictive.

This medicine is not recommended for use in children.

**2. What should I know before I use MYCOTEX?*****When you must not take MYCOTEX***

**Do not take MYCOTEX if you have ever had an allergic reaction to:**

- mycophenolic acid, the active ingredient in MYCOTEX, mycophenolate sodium or mycophenolate mofetil
- any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- faintness
- wheezing or troubled breathing

If you think you may be allergic, ask your doctor for advice without taking MYCOTEX.

**Do not take MYCOTEX if you are pregnant, think you may be pregnant, or intend to become pregnant.**

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

**Do not take MYCOTEX if you are a woman who could be pregnant and you have not provided a negative pregnancy test before your first prescription.**

**Do not take MYCOTEX if you are not using effective contraception.**

Your doctor should advise you about contraception before you start taking MYCOTEX.

Reliable contraception must be used before starting MYCOTEX. MYCOTEX 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 MYCOTEX if you are breast-feeding.**

You must not breast-feed during treatment with MYCOTEX. This is because small amounts of the medicine can pass into the mother's milk.

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

In that case, return it to your pharmacist.

***Before you start to take MYCOTEX*****Tell your doctor if you have or have had:**

- sun spots 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 KelleySeegmiller 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 special precautions if you have any of the above conditions.

**Tell your doctor if you are pregnant, think you may be pregnant or plan 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.

**Tell your doctor if you are breastfeeding.****Tell your doctor if you plan to have any vaccinations.**

**Tell your doctor if you are lactose intolerant.** MYCOTEX tablets contain lactose.

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

Your doctor will want to know if you are prone to allergies.

**3. What if I am taking other medicines?*****Taking other medicines***

**Tell your doctor if you are taking any other medicines, including any 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.

**If you have not told your doctor about any of these things, tell them before you take MYCOTEX.**

**4. How do I use MYCOTEX?**

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

These instructions may differ from the information contained in this leaflet.

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

## **How much to take**

### **Do not exceed the recommended dosage.**

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.

## **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, as long as 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.**

## **When to take MYCOTEX**

Take MYCOTEX twice a day, 12 hours apart if possible.

Taking your doses 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 MYCOTEX**

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

It is important to keep taking MYCOTEX to prevent rejection of your transplanted kidney.

## **If you forget to take MYCOTEX**

**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 one that you missed.**

This may increase the chance of you getting an unwanted side effect.

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

**If you have trouble remembering when 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 number 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much MYCOTEX. Do this even if there are no signs of discomfort or poisoning.**

**Keep the telephone numbers for these places handy.**

## **5. What should I know while using MYCOTEX?**

### **Things you must do**

**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.

**Tell your doctor immediately if you have COVID-19. Increased severity of COVID-19 may occur with MYCOTEX.**

**You must not take this medicine while you are pregnant or breastfeeding. If you become**

**pregnant while taking MYCOTEX, tell your doctor immediately.**

Your doctor will discuss the potential risks of taking MYCOTEX during pregnancy such as miscarriage and a higher risk of birth defects.

**If you are a woman of childbearing 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.**

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.

**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. Tell your doctor immediately if your partner becomes pregnant while you are taking MYCOTEX.**

**Do not breast-feed during treatment with MYCOTEX and for 6 weeks after you have stopped taking MYCOTEX.**

**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 a cancer. Immunosuppressant medicines, including MYCOTEX, 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, MYCOTEX 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 MYCOTEX and for at least 6 weeks after stopping treatment.**

**Men must not donate semen during treatment with MYCOTEX and for at least 90 days after stopping treatment.**

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

**Tell any other doctor, dentist or pharmacist who treats you that you are taking MYCOTEX.**

**Things you must 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 MYCOTEX.

**Do not give this medicine to anyone else even if their condition seems similar to yours.**

**Do not take it to treat any other complaints unless your doctor tells you to.**

**Things to be careful of**

**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 or operate machinery.

## 6. Are there any side effects?

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MYCOTEX, even if you do not think it is connected with the medicine.**

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects. Your doctor may be able to relieve some of the side effects of MYCOTEX by lowering the dose.

**If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.**

As people grow older, they are more likely to get side effects from medicines.

**Do not be alarmed by this list of possible side effects.** You may not experience any of them.

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

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>diarrhoea, constipation, indigestion, flatulence, loose stools, nausea (feeling sick), or vomiting</li> <li>pain in the stomach</li> <li>pain or swelling in the joints</li> <li>weakness</li> <li>muscle pain</li> <li>indigestion, feeling bloated, or tenderness in the abdomen</li> <li>headache, dizziness</li> <li>unusual bleeding or bruising (signs of low level of blood platelets)</li> </ul>	<p><b>Tell your doctor if you notice any of the following and they worry you:</b></p>

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>cough</li> <li>anxiety</li> <li>fever (temperature above 37°C)</li> <li>tiredness</li> </ul> |  |
|---|--|

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>symptoms of infection including fever, chills, sweating, feelings of tiredness, drowsiness, or lack of energy. If you are taking MYCOTEX you may be more susceptible to infections than usual. These may affect various body systems, the most common being the urinary tract, the respiratory tract and the skin.</li> <li>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.</li> <li>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</li> <li>enlarged glands, a new lump or mole on your skin, or changes</li> </ul>	<p><b>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.</b></p>

to existing moles, anywhere on the body. A very small number of MYCOTEX 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.

- any symptoms of anaemia  
  
(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

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

Other side effects not listed here may happen in some people. Some side effects may not give you any symptoms and can only be found when tests are done.

**Do not be alarmed by this list of side effects. You may not experience any of them.**

### 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](http://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

<b>Active ingredient (main ingredient)</b>	Mycophenolic Acid (as Mycophenolate Sodium USP) 360 mg
<b>Other ingredients (inactive ingredients)</b>	<p>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.</p> <p>OPADRY II complete film coating system 85F540054 PINK contains polyvinyl alcohol, titanium dioxide, macrogol, talc, iron oxide yellow and iron oxide red</p> <p>OPACODE monogramming ink S-1-17823 BLACK contains shellac, iron oxide black, and propylene glycol</p>

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

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

**MYCOTEX**

Blister pack: AUST R 391538

Bottle pack: AUST R 391535

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