

CEPTOLATE®

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 taking CEPTOLATE?

CEPTOLATE contains the active ingredient mycophenolate mofetil. CEPTOLATE is used to prevent the rejection of a transplanted organ.

For more information, see Section [1. Why am I taking CEPTOLATE?](#) in the full CMI.

2. What should I know before I take CEPTOLATE?

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

3. What if I am taking other medicines?

Some medicines may interfere with CEPTOLATE 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 CEPTOLATE?

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

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

5. What should I know while taking CEPTOLATE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, surgeon, anaesthetist dentist or pharmacist you visit that you are using CEPTOLATE.• Wear protective clothing and broad-spectrum sunscreen when outdoors.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking 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.• Do not crush CEPTOLATE tablets.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how CEPTOLATE affects you, or if you experience somnolence (drowsiness), confusion, dizziness, tremor or hypotension (low blood pressure).
Looking after your medicine	<ul style="list-style-type: none">• Keep CEPTOLATE tablets in a cool dry place where the temperature stays below 25°C.• Keep your tablets in the original container until it is time to take them.

For more information, see Section [5. What should I know while taking CEPTOLATE?](#) 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.

CEPTOLATE

Active ingredient: Mycophenolate mofetil

Consumer Medicine Information (CMI)

This leaflet provides important information about using CEPTOLATE. 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 CEPTOLATE.

Where to find information in this leaflet:

1. Why am I taking CEPTOLATE?
2. What should I know before I take CEPTOLATE?
3. What if I am taking other medicines?
4. How do I take CEPTOLATE?
5. What should I know while taking CEPTOLATE?
6. Are there any side effects?
7. Product details

1. Why am I taking CEPTOLATE?

CEPTOLATE contains the active ingredient mycophenolate mofetil.

CEPTOLATE 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.

CEPTOLATE may be used together with other medicines known as ciclosporin and corticosteroids.

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.

2. What should I know before I take CEPTOLATE?

Warnings

Do not take CEPTOLATE if:

- you are allergic to mycophenolate mofetil, or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include:

- o chest tightness, wheezing or difficulty breathing
- o severe dizziness or light-headedness
- o swelling of the face, lips, tongue, throat or other parts of the body with difficulty breathing
- o skin rash, itching or hives (raised red patches of skin that are often very itchy)

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

- you are pregnant**

- o CEPTOLATE is harmful to an unborn baby when taken by a pregnant woman.
- o There have been cases of miscarriage and severe birth defects reported when patients have taken CEPTOLATE during pregnancy.
- o You must tell your doctor if you are pregnant or plan to become pregnant.

- you are breast feeding**
 - o CEPTOLATE 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**
 - o You must use two reliable forms of contraception at the same time before beginning CEPTOLATE therapy, during therapy, and for at least six weeks after stopping CEPTOLATE, 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.**
 - o If you take this medicine after the expiry date has passed it may not work as well.

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

Check with your doctor if you:

- are a sexually active man**

- o you are recommended to use condoms during treatment and for 90 days after stopping treatment, even if you have had a vasectomy.
- o your female partner(s) are recommended to use reliable contraception while you are being treated with CEPTOLATE and for 90 days after you have stopped taking CEPTOLATE.
- o you should not donate semen while you are being treated with CEPTOLATE and for 90 days after you have stopped taking CEPTOLATE.

- have any other health problems, especially the following:**

- o a history of sun spots or skin cancers
- o a history of low blood counts of neutrophils (a type of white blood cell)
- o a history of serious stomach or bowel problems (such as ulcers or bleeding)
- o rare diseases due to a deficiency of the HGPRT enzyme such as Lesch-Nyhan or Kelley-Seegmiller syndrome
- o kidney disease
- o have allergies to any other medicines, foods, preservatives or dyes.

You should not donate blood while you are being treated with CEPTOLATE and for at least 6 weeks after you have stopped taking CEPTOLATE.

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 CEPTOLATE.

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

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

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

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 CEPTOLATE 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
- aciclovir, ganciclovir, valaciclovir or valganciclovir - used to treat certain viral infections
- isavuconazole - used to treat fungal infections
- antacids - used to treat heartburn and indigestion
- colestyramine - used to treat high cholesterol
- ciprofloxacin, amoxicillin plus clavulanic acid, norfloxacin plus metronidazole and rifampicin - 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 CEPTOLATE 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 CEPTOLATE.

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

4. How do I take CEPTOLATE?

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

Take CEPTOLATE exactly as your doctor has prescribed.

Your doctor will tell you how many CEPTOLATE tablets to take each day.

Adults

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).

Your doctor may adjust your dose depending on your response.

How to take it

Swallow the tablets whole with a full glass of water.

Do not crush the tablets.

When to take CEPTOLATE

It is best to take doses of CEPTOLATE approximately 12 hours apart.

Taking CEPTOLATE 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 CEPTOLATE

CEPTOLATE should be taken every day. It is important to keep taking CEPTOLATE to ensure your transplanted organ keeps working properly.

Continue taking CEPTOLATE for as long as your doctor tells you.

If you forget to take CEPTOLATE

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 each dose as you would normally.

Do not take a double dose to make up for the dose that 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 CEPTOLATE

If you think that you or anyone else has taken too much CEPTOLATE, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (**Australia telephone 13 11 26**) for advice, 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 CEPTOLATE?

Things you should do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking CEPTOLATE.

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 CEPTOLATE. If you are a woman of child bearing potential, you must use two reliable forms of contraception at the same time before beginning CEPTOLATE therapy, during therapy and for at least 6 weeks after stopping CEPTOLATE 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 CEPTOLATE and for 90 days after you have stopped receiving CEPTOLATE.

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.

Keep all of your doctor's appointments 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 CEPTOLATE or change the dose without first checking with your doctor.
- Do not take CEPTOLATE 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 CEPTOLATE tablets.
- Do not take any other medicines whether they require a prescription or not without first checking with your doctor or pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CEPTOLATE affects you or if you experience somnolence (drowsiness), confusion, dizziness, tremor, lightheadedness or hypotension (low blood pressure).

CEPTOLATE may affect your ability to drive a car or operate machinery.

Looking after your medicine

- Keep your tablets in the original container until it is time to take them.
- Store below 25°C.

Store CEPTOLATE 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.

Heat or dampness can destroy some medicines.

Keep CEPTOLATE 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.

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 or if the packaging is torn or shows signs of tampering.

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 taking CEPTOLATE 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.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">diarrhoea, constipation, nausea (feeling sick), vomiting or indigestionstomach, chest or back painheadacheurinary infectionsacnehair loss or itchy skin	Speak to your doctor if you have any of these less serious side effects and they worry you.

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 stoolsunexpected bruising or bleedingsigns of anaemia such as excessive tiredness, dizziness or looking paleswelling of the hands, ankles, feet or lymph nodesinability 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 often very itchy)breathing difficulties, pain in the chest, chronic cough with blood	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.

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 not listed here 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 else that may be 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.

7. Product details

This medicine is only available with a doctor's prescription. CEPTOLATE is not addictive.

CEPTOLATE tablets

CEPTOLATE 500 mg tablets come in packs of 50 tablets.

Active ingredient (main ingredient)	mycophenolate mofetil (500 mg)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">microcrystalline cellulosepregelatinised maize starchpovidonesilicon dioxidemagnesium stearatesodium lauryl sulfatecroscarmellose sodiumOPADRY II Complete Film Coating System 85F94410 Pink (ARTG No. 106325)

CEPTOLATE tablets are light pink film coated, oval, biconvex, bevelled edge tablets debossed with MYLAN on one side of the tablet and 472 on the other side reverse. (AUST R 163308).

Who distributes CEPTOLATE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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