

CEPTOLATE

mycophenolate mofetil

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CEPTOLATE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CEPTOLATE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CEPTOLATE is used for

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.

CEPTOLATE is not addictive.

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

Before you take CEPTOLATE

When you must not take it

Do not take CEPTOLATE if:

1. you have an allergy to:

- any medicine containing mycophenolate mofetil
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

2. you are pregnant

- CEPTOLATE 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 CEPTOLATE during pregnancy

You must tell your doctor if you are pregnant or plan to become pregnant.

3. you are breastfeeding

- CEPTOLATE may pass into human breast milk and could

cause serious side effects in your baby if you breastfeed

4. 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 CEPTOLATE therapy, during therapy and for at least 6 weeks after stopping CEPTOLATE, unless you are not sexually active

5. the packaging is torn or shows signs of tampering

6. the expiry date printed on the pack has passed

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if:

1. you are pregnant or plan 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

2. you are breast-feeding or plan to breast-feed

3. 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 CEPTOLATE and for 90 days after you have stopped taking CEPTOLATE
 - you should not donate semen while you are being treated with CEPTOLATE and for 90 days after you have stopped taking CEPTOLATE
- 4. you should not donate blood while you are being treated with CEPTOLATE and for at least 6 weeks after you have stopped taking CEPTOLATE**
- 5. you 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 ulcers or bleeding)
 - rare diseases due to a deficiency of the HGPRT enzyme such as Lesch-Nyhan or Kelley-Seegmiller syndrome
 - kidney disease
- 6. you have allergies to any other medicines, foods, dyes or preservatives**

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

Taking other medicines

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

Some medicines and CEPTOLATE may interfere with each other. 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, medicines used to treat certain viral infections
- isavuconazole, a medicine used to treat fungal infections
- antacids, medicines used to treat heartburn and indigestion
- colestyramine, a medicine used to treat high cholesterol
- ciprofloxacin, amoxicillin plus clavulanic acid, norfloxacin plus metronidazole and rifampicin, medicines used to treat infections
- iron supplements, medicines 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, medicines used to treat indigestion and stomach ulcers such as lansoprazole and pantoprazole
- calcium-free phosphate binders (such as sevelamer), medicines 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 this medicine.

How to take CEPTOLATE

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

They may differ from the information contained in this leaflet.

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

How much to take

Take CEPTOLATE exactly as your doctor has prescribed.

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

Adults

The dose to prevent organ rejection is usually 1 g to 1.5 g in this morning and 1 g to 1.5 g at night (2 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 capsules or tablets whole with a full glass of water.

Do not crush the tablets or open or crush the capsules.

If a capsule breaks open accidentally, wash any powder off your skin thoroughly with soap and water.

When to take it

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

Take your medicine at about the same time each day.

Taking it 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 it

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 it

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 your medicine 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much CEPTOLATE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking CEPTOLATE

Things you must 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 must not do

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 stop taking your medicine or change the dose without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not open CEPTOLATE capsules or crush CEPTOLATE tablets.

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

Things to be careful of

Be careful driving or operating machinery until you know how CEPTOLATE affects you or if you experience sleepiness, drowsiness, confusion, dizziness, lightheadedness or tremor.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CEPTOLATE.

This medicine helps most people who have an organ transplant, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the 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.

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.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- diarrhoea, constipation, nausea (feeling sick), vomiting or indigestion
- stomach, chest or back pain
- headache
- urinary infections

The above list includes the more common side effects of your medicine.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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, feet or lymph nodes
- hypersensitivity
- breathing difficulties, pain in the chest, a long-term cough with blood

The above list includes serious side effects. You may need urgent

medical attention. Serious side effects are rare.

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.

After using CEPTOLATE

Storage

Keep your capsules or tablets in the pack until it is time to take them.

If you take the capsules or tablets out of the pack they may not keep well.

Keep your capsules or tablets in a cool dry place where the temperature stays below 25°C.

Do not store CEPTOLATE 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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Ceptolate Capsules

Oblong capsules, caramel on one end and lavender on the other, printed with black ink MYLAN over 2250 on both the cap and body.

Available in packs of 50.

Ceptolate Tablets

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.

Available in packs of 50.

Ingredients

Ceptolate Capsules

Each capsule contains 250 mg of mycophenolate mofetil.

Inactive ingredients:

The capsule fill contains:

- microcrystalline cellulose
- pregelatinised maize starch
- silicon dioxide
- magnesium stearate
- sodium lauryl sulfate
- croscarmellose sodium

The capsule shell contains:

- gelatin
- sodium lauryl sulfate
- shellac
- ammonium hydroxide
- sorbitan monolaurate
- Empty Hard Gelatine Capsule Size 1 Lavender Op/Caramel OP G1HCSA00612 (ARTG No 106636)

The dyes in the capsule shell are:

- indigo carmine (132)
- iron oxide red (172)
- titanium dioxide (171)
- iron oxide yellow (172)
- iron oxide black (172)
- OPACODE monogramming ink S-1-17822 Black (ARTG No. 12390)
- OPACODE monogramming ink S-1-17823 Black (ARTG No. 12108)

Ceptolate capsules are gluten and lactose free.

Ceptolate Tablets

Each tablet contains 500 mg of mycophenolate mofetil.

Inactive ingredients:

- microcrystalline cellulose
- pregelatinised maize starch
- povidone
- silicon dioxide
- magnesium stearate
- sodium lauryl sulfate
- croscarmellose sodium
- OPADRY II Complete Film Coating System 85F94410 Pink (ARTG No. 106325)

Ceptolate tablets are gluten and lactose free.

Supplier**Alphapharm Pty Ltd**

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australia registration numbers:

CEPTOLATE 250 mg capsules -
AUST R 165766

CEPTOLATE 500 mg tablets -
AUST R 163308

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