



Australian
Rheumatology
Association

PATIENT INFORMATION ON

MYCOPHENOLATE

MOFETIL

(Brand name: CellCept)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **How you should take your medicine;**
- **What are the possible side effects;**
- **What tests you must have to monitor your condition and to detect unwanted effects; and**
- **Other precautions you should take.**

Please read it carefully and discuss with your doctor.

What is mycophenolate ?

Mycophenolate mofetil (brand name CellCept) is a medicine used to treat immune related diseases such as rheumatoid arthritis, systemic lupus erythematosus (also known as lupus or SLE), inflammatory bowel disease such as Crohn's disease, and other kidney or skin disorders. It is also used to prevent transplant rejection in people who have received transplanted organs such as kidneys.

It is an immunosuppressive medicine, which means that it works by reducing the activity of the immune system. In rheumatoid arthritis, this action helps to reduce inflammation in the joints and thus reduce pain and swelling.

For more information about rheumatoid arthritis or systemic lupus erythematosus (SLE/Lupus) see the Arthritis Australia website

www.arthritisaustralia.com.au/index.php/arthritis-information/information-sheets.html

What benefit can you expect from your treatment?

Mycophenolate is useful in many autoimmune diseases. It does not work straight away. Reduced symptoms may be noticed after 4 weeks. The effects to delay or prevent joint or other organ damage may take several months.

Other medicines may be given to improve your symptoms while waiting for this medicine to work.

How is mycophenolate taken?

Mycophenolate is taken by mouth as a tablet usually twice a day. Taking the medicine in the evening or at meal times may help to reduce nausea (see possible side effects). It can be given as a liquid if the tablets are hard to swallow.

What is the dosage?

Tablets come in strengths of 250mg or 500mg. The liquid contains 1g in 5mls.

Treatment usually starts with a low dose, which is increased and adjusted depending on the response and side effects. The usual maximum dose is up to 2 to 3g every day.

Are other medicines taken with mycophenolate?

Mycophenolate may be taken in combination with other arthritis medicines, including:

- other DMARDs;

- steroid medicines such as prednisolone or cortisone injections into the joint;
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen/Nurofen); and/or
- simple pain medicines such as paracetamol.

How long is the treatment continued?

The treatment may be continued indefinitely as long as it is effective and as long as no serious side effects occur.

If mycophenolate treatment is stopped for more than a few weeks, there is a risk that your condition may worsen. Continue with your treatment unless advised by your doctor or unless side effects develop.

Are there any possible side effects?

Below are possible side effects that you might experience with your treatment. Tell your doctor if you experience any side effects.

If you do experience side effects, a reduction in dose may minimise these so that you can continue to take the medicine. Your doctor will advise on any dose changes that are necessary.

Tell your doctor if you experience any possible side effects.

Most common possible side effects:

- The most common side effects are *nausea*, *vomiting* and *diarrhoea*. These can be reduced if mycophenolate is taken with food or in the evening. Antinausea tablets can be used if needed.
- Headache, dizziness, difficulty sleeping, tremor and rash can occur.
- Patients older than 65 may be at increased risk of some side effects, especially infections and gastrointestinal bleeding.
- People who have had ulcers or other serious gastrointestinal conditions should talk with their doctors before taking this medicine.

Less common or rare possible side effects:

There are some rare but potentially serious side effects with mycophenolate.

- **Blood counts:** Mycophenolate can rarely cause a drop in the number of white blood cells, which are needed to fight infection. It can also cause a drop in the number of platelets, which help to stop bleeding. Very rarely red cells can be affected.

Regular blood tests aim to pick these problems up early if they occur. However, if you develop a sore mouth, mouth ulcers, easy bruising, nosebleeds, bleeding gums, breathlessness, infection or fever tell your doctor straight away.

- **Liver:** Mycophenolate can inflame the liver causing a type of hepatitis. Regular blood tests aim to pick this up early if it occurs.

The dose of mycophenolate may need to be reduced or stopped if problems occur.

Liver problems may be increased when mycophenolate is combined with the medicines azathioprine (Azahexal, Imuran), leflunomide (Arava), or with heavy alcohol use (see *Alcohol* overleaf).

- **Cancer:** see below.

Long term possible side effects:

Mycophenolate may be taken for long periods to manage immune conditions. In addition to possible effects mentioned above, the following are rare but possible long term side effects, or long term issues that may concern patients:

- **Cancer:** Studies of transplant patients taking mycophenolate have found it may increase risk of some cancers such as lymph node cancers (lymphomas) and skin cancers (see *Precautions*). There may be a similar risk in people with rheumatic conditions who take mycophenolate for long periods of time. You should discuss this issue with your rheumatologist before starting the medicine. For general cancer prevention, stopping smoking is recommended.
- Mycophenolate **does not** affect a person's ability to have children in the long term. See also *Precautions* overleaf.

More information about possible side effects

Information that comes with your mycophenolate will also outline in detail potential serious side effects. Many of those side effects relate to the use of **higher doses** used to prevent transplant organ rejection. These may not be applicable to the much lower doses that are prescribed for the treatment of rheumatoid arthritis. Talk to your doctor if you have concerns about any possible side effects.

What precautions are necessary?

Blood tests:

- Since the liver and blood cells may be affected by mycophenolate, you **must** have regular blood tests during your treatment. This is very important, as you may not get symptoms with some of these problems.
- As well as monitoring for side effects, blood tests help to monitor your condition to determine if the treatment is effective.
- You will need to have full blood counts and liver function tests every 2 to 4 weeks for the first few months of treatment and then every 1 to 3 months after that.
- If there are no problems seen after 3 months of treatment at a specific dose of mycophenolate, the blood tests may be done less frequently.
- Your general practitioner will be informed about the monitoring schedule. It is important to see your general practitioner if you have been asked to do so as they have an important role to play in monitoring your condition.

Avoid infections:

- Because your immune system may be depressed, there is an increased risk of developing some infections, especially herpes zoster (chicken pox and shingles). You should try to avoid contact with people who have these infections. If you have an infection or persistent fever, tell your doctor straight away.

Other medicines:

- Mycophenolate can interact with other medicines. You should tell your doctor (including your general practitioner, rheumatologist and others) about all

medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines.

You should also mention your treatment when you see other health professionals.

- Some medicines that may interfere with mycophenolate include:
 - acyclovir (Zovirax)
 - azathioprine (Imuran)
 - antacids containing magnesium or aluminum hydroxide (e.g. Mylanta)
 - oral contraceptives
 - trimethoprim/sulfamethoxazole (Bactrim)
 - theophylline (Theo-Dur)
 - phenytoin (Dilantin)
 - probenecid (Procid)
- Aspirin can be used safely in the low doses taken for prevention of heart attack and stroke.
- Mycophenolate can be taken safely with anti-inflammatory drugs (NSAIDs), as long as your kidney function is normal.
- Combined medicines, such as Panadeine and Panadeine Forte, can be used safely while taking mycophenolate provided you take them as directed.
- Because many antacids interfere with the absorption of mycophenolate, they should not be taken at the same time. ***Instead, you should take antacids at least 1 hour before mycophenolate or 2 hours after taking mycophenolate.***
- Some vaccinations should be avoided while taking this medication. Be sure to discuss with your doctor before receiving any vaccines.

Alcohol:

- It is not known precisely what level of drinking is safe when on mycophenolate. However, there is general agreement that 1 to 2 standard drinks taken once or twice a week is unlikely to cause a problem. Drinking more than 4 standard drinks on one occasion, even if infrequently, is strongly discouraged.

Surgery:

- It is not clear whether continuing during surgery changes wound healing or

increases infection. Notify your doctor before planning any surgery.

Pregnancy and breastfeeding:

- Mycophenolate should not be taken during pregnancy.
- If you are pregnant or are considering having a child, you should discuss this with your doctor before beginning this medicine.
- Use an effective form of birth control while taking this medicine and for up to six weeks after you stop taking it.
- Mycophenolate may reduce the blood levels of some oral contraceptives. It is not known if this decreases their effectiveness,

however it is recommended that other forms of birth control be used while taking mycophenolate.

- Do not breast-feed while taking mycophenolate because the drug may be passed into the breast milk.

Skin cancer prevention:

- When taking mycophenolate, it is important to use a sunscreen and avoid prolonged sun exposure. A yearly skin check is recommended.

All patients taking mycophenolate should be seen regularly by a rheumatologist or an immunologist to optimise treatment and to minimise any potential side effects. You must have regular blood tests when taking this medicine. Failure to do so will increase your risk of side effects.

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details:

REMEMBER – Keep all medicines out of reach of children

The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA.

The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.

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