



PATIENT INFORMATION ON

MYCOPHENOLATE MOFETIL

(Brand name: CellCept/Imulate/Ceptolate)

AND MYCOPHENOLATE SODIUM

(Brand name - Myfortic)

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**
- **other precautions you should take while you are taking mycophenolate.**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking mycophenolate you should see your rheumatologist or other specialist regularly to make sure the treatment is working and to minimise any possible side effects.
- You should have regular blood tests as directed by your specialist.
- If you are worried about any side effects you should contact your specialist as soon as possible.

For more information about RHEUMATOID ARTHRITIS, SYSTEMIC LUPUS ERYTHEMATOSUS (SLE/Lupus) and other inflammatory conditions see Arthritis Australia's website www.arthritisaustralia.com.au

What is mycophenolate?

Mycophenolate mofetil (brand name CellCept, Imulate, Ceptolate) and mycophenolate sodium (brand name Myfortic) are both converted to mycophenolic acid, which is used to treat immune related diseases such as systemic lupus erythematosus (also known as lupus or SLE), autoimmune vasculitis (inflammation of blood vessels), 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, heart and liver.

It is an immunosuppressive medicine, which means that it works by reducing the activity of the immune system. In kidney disease caused by SLE, this action helps to reduce inflammation in the kidneys and thus reduce protein loss in urine and helps stabilize kidney function.

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 four weeks. The effects to delay or prevent damage may take several months.

Treatment with mycophenolate may be continued indefinitely as long as it is effective and as long as no serious side effects occur.

If you stop mycophenolate treatment 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.

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. Breaking or crushing of tablet should be avoided.

Mycophenolate mofetil (Cellcept) tablets come in strengths of 250mg or 500mg. The liquid contains 1g in 5mls.

Mycophenolate sodium (Myfortic) tablets come in strengths of 180mg or 360mg.

Treatment usually starts with a low dose, which is increased and adjusted depending on the response and side effects. The usual maximum daily dose is up to 2 to 3g of Cellcept or 1.440g (4 x 360mg tablets) to 2.160g (6 x 360mg tablets) of Myfortic.

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

- other disease modifying anti-rheumatic drugs (DMARDs)
- steroid medicines such as prednisolone or cortisone injections into the joint
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen/Nurofen)
- simple pain medicines such as paracetamol.

There are separate information sheets for the medicines mentioned above.

Are there any side effects?

You might experience side effects with your treatment. Tell your doctor if you are concerned about possible side effects.

A reduction in dose may minimise side effects so that you can continue to take the treatment. Your doctor will advise on any dose changes that are necessary.

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* overleaf). 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

The information sheet 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.

Risk of 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.

Use with 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)
 - Antibiotics like Ciprofloxacin and Amoxicillin+ Clavulanic Acid
 - oral contraceptives
 - 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 or 2 hours after** taking mycophenolate.
- If you are taking mycophenolate it is recommended you should not be immunised with 'live' vaccines such as MMR (measles, mumps and rubella), OPV (oral polio vaccine), BCG (Bacillus Calmette Guerin) or yellow fever. Talk to your doctor before receiving any vaccines.
- Annual Influenza vaccine is recommended.

Use with 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.

Hypersensitivity

Mycophenolate should not be given to patients with known hypersensitivity to the drug

Surgery

- It is not clear whether continuing during surgery changes wound healing or increases infection. Notify your doctor before planning any surgery.

Use in pregnancy and breastfeeding

- Mycophenolate should not be taken during pregnancy as it is a powerful teratogen (i.e. causes malformation of foetus or embryo)
- If you are pregnant or are considering having a child, you should discuss this with your doctor before beginning this medicine.

Your doctor may want to perform a urine pregnancy test (if you are of child bearing age) before starting mycophenolate to exclude unintended exposure of embryo to the drug

- 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.
- More detailed information is available at <https://rheumatology.org.au/gps/documents/ARAPregnancyPrescribingGuidanceupdateApr19.pdf>

Contraception in men taking Mycophenolate

The available evidence does not indicate an increased risk of malformation or miscarriage if the father takes mycophenolate. However the risk cannot be completely excluded. As a precaution you or your female partner are recommended to use reliable contraception during treatment and for 90 days after you stop taking mycophenolate

Skin cancer prevention

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

How to store mycophenolate

- Store mycophenolate tablets at room temperature, away from heat, moisture and light (e.g. not in the bathroom).
- Keep all medicines out of reach of children.

Questions?

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

Your doctor's contact details

If you are taking mycophenolate you should see your rheumatologist or other specialist regularly to optimise treatment and to minimise any potential side effects.

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.