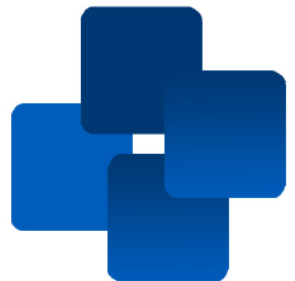


Patient Information

Mycophenolate Products

Important Safety Information

Renal Department



Introduction

The purpose of this leaflet is to give important safety information about mycophenolate products which include mycophenolate mofetil (MMF) and mycophenolate Sodium (for example Myfortic or Ceptava).

What are these medicines used for?

These medicines are widely used

- As an anti-rejection medicine (immunosuppressant) in people who have an organ transplant.
- To dampen down the immune system in people with some autoimmune diseases.

There is some important information you need to know about pregnancy or fathering children whilst taking mycophenolate.

It is known that mycophenolate products can cause birth defects in the unborn baby of mothers who are, or have recently been, taking mycophenolate. For this reason, women are advised **not to become pregnant whilst taking mycophenolate and for 6 weeks after stopping.**

There is advice published for men taking mycophenolate from the Medicines and Healthcare products Regulatory Agency (MHRA) who regulate the medicines available in the UK.

Current published research shows that the outcomes of pregnancies where the father is taking mycophenolate are actually similar to those where men were not taking it. However, there are two theoretical concerns:

- 1) Mycophenolate might affect your sperm and increase the risk of a birth defect in your child.
- 2) Mycophenolate in your semen might expose your partner to similar risks to those seen in women who take the medicine.

For these reasons, it is recommended that your partner use highly effective and reliable contraception while you are taking mycophenolate and for 90 days (13 weeks) after you have stopped this medicine.

Reliable methods of contraception

- Barrier methods, such as condoms and diaphragm when supplemented with spermicide.
- Hormonal implants.
- Oral or injected combined hormonal contraceptives (the pill).
- Certain intrauterine devices (the coil – check with family planning clinic).
- Tubal ligation (female sterilisation).
- Vasectomy (male sterilisation).

The existing advice from the MHRA for women, and the new advice for men taking mycophenolate, are summarised on the next pages, 4 and 5.

Information for women who could become pregnant

- Do **not stop** taking mycophenolate without speaking to a member of the Kidney Team, even if you think that you have become pregnant.
- We now know that approximately one in four children born to women who are taking mycophenolate will have a birth defect. Up to half of pregnant women taking mycophenolate will have a miscarriage. Both of these figures are much higher for mycophenolate compared with women who take other anti-rejection medicines or in those not taking mycophenolate.
- Before you start mycophenolate you will be asked to do **two** pregnancy tests 8 to 10 days apart. Where possible, treatment will only be started if these are negative.
⇒ **Date of pregnancy test 1:** _____
⇒ **Date of pregnancy test 2** (8 to 10 days later): _____
- While taking mycophenolate (and for at least 6 weeks after stopping) you should use **two** reliable forms of contraception.
- Do **not donate blood** whilst having treatment, or for 6 weeks after stopping treatment.

Information for men whose partner could become pregnant

- Do **not stop** taking mycophenolate without speaking to a member of the Kidney Team, even if you think that your partner has become pregnant.
- For sexually active men (including those who have had a vasectomy), condoms should be used during treatment and for 90 days (13 weeks) after your last dose of mycophenolate to prevent mycophenolate being passed to your female partner.
- Female partners of male patients treated with mycophenolate should use reliable contraception during the treatment and for 90 days (13 weeks) after your partner's last dose.
- Men should **not donate sperm** during treatment or for 90 days (13 weeks) after your last dose.
- Do **not donate blood** whilst having treatment, or for 6 weeks after stopping treatment.

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If I am taking mycophenolate and want to try for a baby, what are my options?

It is important that you talk to your consultant or a member of the Kidney team **before** trying for a baby. If you are a man or a woman taking mycophenolate, it may be possible for you to change to an alternative medicine.

In transplantation, we recommend that both male and female patients who are taking mycophenolate wait one or two years after your transplant before considering a switch of anti-rejection medicines in order to try for a baby. This helps to ensure the following:

- Any risk of rejection with the medicine switch is minimal.
- You are on the lowest doses of anti-rejection medicine possible.
- Your transplant function is stable.

When taking mycophenolate for an autoimmune disease

For people taking mycophenolate for an autoimmune disease we recommend that you have a discussion with your consultant in clinic **before** trying for a baby. Your consultant will assess how active your disease is as it is important that you only try for a baby if your disease is well controlled. Your consultant will discuss the possibility of switching to an alternative treatment to mycophenolate.

Further information

Please also read the leaflet inside your medication box for more information about mycophenolate.

Questions

Please speak to one of the transplant/renal team if you have any questions or concerns about mycophenolate products and pregnancy, or about any of the information in this leaflet.

Please use this space to write down any notes or questions you may like to ask:

Useful Contact details

Lister Renal Unit - Outpatient department:

Post Transplant Co-ordinators **☎** 01438 286363
or e-mail: posttransplantcoordinators.enh-tr@nhs.net

Renal Pharmacy Team **☎** 01438 284677
or e-mail: renalpharmacists.enh-tr@nhs.net

Dr Thompson's secretary – Nephrology patients **☎** 01438 284309

Dr Fluck's secretary – Transplant patients **☎** 01438 284362

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