Mycophenolate products – important safety information

You are receiving this letter because you have been or are planning to start a medicine called mycophenolate. Mycophenolate products include mycophenolate mofetil (MMF) or mycophenolate sodium (Myfortic). These medicines are widely used:

- as an anti-rejection medicine (immunosuppressant) in people who have an organ transplant,
- to dampen down your 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. It is for this reason **women are advised not to become pregnant whilst taking mycophenolate and for 6 weeks after stopping**.

There has been some recent advice for men taking mycophenolate from the UK Medicines Regulator (MHRA, which licenses all medicines).

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. The first is that mycophenolate might affect your sperm and increase the risk of a birth defect in your child. The second is that mycophenolate in your semen might expose your partner to similar risks to those seen in women who take the medicine. For this reason **it is recommended that your partner should also use a highly effective and reliable form of contraception whilst you are taking mycophenolate and until 90 days (13 weeks) after you have stopped this medicine**.

The existing advice from the MHRA for women, and the new advice for men taking mycophenolate, are summarised below.

**Information for women who could become pregnant**

- Do not stop taking mycophenolate without speaking to a member of transplant/renal 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 with mycophenolate compared with women who take other anti-rejection medicines or in those who do not take mycophenolate.
- Before you start mycophenolate you will be asked to do 2 pregnancy tests 8-10 days apart. Where possible, treatment will only be started if these are negative.
  - Date of pregnancy test 1 ...........................................
  - Date of pregnancy test 2 (8-10 days later) ....................
- While taking mycophenolate (and for at least 6 weeks after stopping) you should use **two** reliable forms of contraception.
• Reliable methods of contraception include:
  o Barrier methods (condoms, diaphragm) when supplemented with spermicide
  o Tubal ligation (sterilisation)
  o Hormonal implants
  o Oral or injected combined hormonal contraceptives (the pill)
  o Certain intrauterine devices (the coil – check with family planning clinic)
  o Male sterilisation

• Do not donate blood during 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 transplant/renal 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 avoid mycophenolate being passed to your female partner.
• Female partners of male patients treated with mycophenolate should use reliable contraception during treatment and for 90 days (13 weeks) after your last dose.
• Men should not donate sperm during therapy or for 90 days (13 weeks) after your last dose of mycophenolate.
• Do not donate blood during or for 6 weeks after stopping treatment.

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 transplant/renal 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 that

• 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.

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 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.

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

Useful telephone numbers for Oxford Transplant Centre out-patient department:-

Transplant Nurse Practitioners ☎ 01865 228662

Renal Pharmacy Team ☎ 01865 226105