New Advice on Mycophenolate and Pregnancy

Information for you

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Mycophenolate (Mycophenolate Mofetil (Cellcept® and Mycophenolic acid (Myfortic®)) are used as anti-rejection medicine in transplant and in autoimmune diseases to dampen down your immune system. There is some important information you need to be aware of regarding pregnancy or fathering children while taking mycophenolate.

It is known that mycophenolate can cause birth defects in the unborn baby of mothers taking mycophenolate. It is for this reason that women are advised **not to become pregnant whilst taking mycophenolate**.

There has been some recent advice for men taking mycophenolate from the UK Medicines Regulator (MHRA), which licenses all medicines as there is a concern that mycophenolate might affect your sperm leading to a risk of birth defects in your child.

**It is now recommended that men who take mycophenolate always wear a condom when having sex with a woman who might become pregnant. This applies even if you have had a vasectomy. This also applies for 90 days after stopping mycophenolate, if after discussion with your renal consultant you both agree to change to another medication.**
It is recommended that your partner should also use an effective form of contraception while you are taking mycophenolate and for 90 days after you have stopped this medicine.

It must be stressed that these are precautionary measures. Current evidence is that the outcomes of pregnancies where the father is taking mycophenolate are similar to those of the general population.

At present there is no known pattern of birth defects in the children of men who were taking mycophenolate.

It is important that the medicines you are taking are safe for your unborn baby.
Female patients taking mycophenolate:

• Do not stop taking mycophenolate without speaking to the transplant/renal team.

• Women of child bearing age must use 2 reliable types of contraception (e.g. implant or coil and condoms or diaphragms) while taking mycophenolate and for at least 6 weeks after your last dose of mycophenolate.

• Talk to the transplant or renal team immediately if you think you could be pregnant. There are other transplant and immune medicines that can be used in its place.

• If you are planning to become pregnant please discuss with the transplant or renal team so that your medication can be changed. Each case needs to be considered on an individual basis.

• We now know that approximately 1 in 4 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 transplant and immune medicines or who do not take mycophenolate.
Male patients taking mycophenolate:

For male patients taking mycophenolate we have previously advised that there is no risk to the unborn baby. This is based on 20 years of experience with this medicine and is supported by Transplant Registry reports. These reports show that the outcomes of pregnancies fathered by men taking mycophenolate are the same as those in the general population.

The new advice for men taking mycophenolate is based on a theoretical risk to the unborn baby. This risk is very small but we have to make you aware of this change. The new advice for men, from the UK Medicines Regulator (MHRA) is:

• **Do not stop taking mycophenolate without speaking to a member of the transplant or renal team.**

• Sexually active men (including men who have had a vasectomy), always use condoms during and for 90 days after your last dose of mycophenolate.

• Female partners should also use effective contraception during this time.

• Men should not donate sperm during or for 90 days after your last dose of mycophenolate.
• Talk to the transplant or renal team if you are planning on starting a family. There are other transplant and immune medicines that can be used in its place.

• It is important that for men taking mycophenolate who wish to father a child these theoretical risks should be balanced against the risk of transplant rejection or disease relapse.

Talk to the transplant or renal team if you intend to father a child or if you have any questions or concerns about the information in this leaflet.

Useful telephone numbers for University Hospital Crosshouse Renal Department:

Linda Easton, Renal Administrator ☎️ 01563 827491
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