

PATIENT GUIDE

MYCOPHENOLATE: Risks of Miscarriage and Birth Defects

Key points to remember:

- **Mycophenolate causes birth defects and miscarriages**
- **Follow the contraceptive advice from your doctor to avoid accidental pregnancy**
- **Before you start taking mycophenolate, ask your doctor to explain again if you do not fully understand the information you have been given**
- **Do not stop taking mycophenolate without talking to your doctor**
- **Mycophenolate should not be taken by women who are breastfeeding**
- **This medicine is only for you – do not give it to anyone else because it might harm them**

If you are treated with a medicine containing mycophenolate and can become pregnant, your prescriber will talk to you and answer any questions you have about:

- the risks of mycophenolate for an unborn baby
- how to avoid these risks with contraception (birth control)
- pregnancy planning

This guide will help you to remember the information you have discussed with your doctor. Keep it safe so that you can refer to it again. Also, read the package leaflet supplied with your medicine for full information on mycophenolate.

1. Is this information relevant to me?

You need to be particularly aware of the risks of mycophenolate for an unborn baby if you are a pregnant woman or could become pregnant. This includes girls who have entered puberty and all women who have a womb and have not passed through the menopause. You also need to be aware of the risks if you are breastfeeding.

2. What are the risks?

Mycophenolate has an increased risk of miscarriage or birth defects (problems that happen while a baby is developing in the mother's body).

The exact reason why this happens is not clear but the risk is greater in pregnant patients taking mycophenolate than those taking other immunosuppressants (medicines that weaken the body's immune system) and much greater than the risk in the general population.

The birth defects that can occur include:

- abnormalities of the ears, eyes, face, fingers, kidneys or oesophagus (the part of the digestive tract connecting the mouth with the stomach)
- congenital heart diseases (that is, heart diseases present from birth)
- congenital disorders of the nervous system such as spina bifida (a condition where the backbone does not develop properly in an unborn baby)

3. How likely is it that my unborn baby will be harmed?

Studies have shown that around half (45 to 49%) of all pregnancies in women taking mycophenolate end in miscarriage. This compares with 12 to 33% in women taking other immunosuppressants and 15-20% in the general population.

Around a quarter (23 to 27%) of babies born to women taking mycophenolate during pregnancy are born with birth defects. This compares with 4 to 5% for women taking other immunosuppressants following transplantation, and 2 to 3% in the general population.

What should I do?

Information for women and men is presented separately

Important information for WOMEN

Key points to remember:

- **Mycophenolate causes birth defects and miscarriages**
- **Follow the contraceptive advice from your doctor to avoid accidental pregnancy**
- **Before you start taking mycophenolate, ask your doctor to explain again if you do not fully understand the information you have been given**
- **Do not stop taking mycophenolate without talking to your doctor**
- **Mycophenolate should not be taken by women who are breastfeeding**
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Pregnancy tests

If you are capable of becoming pregnant, you will need to have a pregnancy test before starting treatment with mycophenolate. Your doctor will explain the type and timing of the pregnancy tests that need to be carried out before and during treatment with mycophenolate. Your doctor will recommend two blood or urine pregnancy tests; the second test should usually be carried out 8 to 10 days after the first one and immediately before you start taking mycophenolate. The timing of the second test can depend on the type of transplant donor. Your doctor might suggest repeating these tests at certain times (e.g. if there has been a gap in the use of effective contraception). Your doctor will discuss the results of all pregnancy tests with you.

Contraception

To make sure you do not become pregnant, use effective contraception (birth control) while you are taking mycophenolate and for at least 6 weeks after your last dose. If you have sex with a man, you must use one form of effective contraception, unless abstinence is the chosen method of contraception. Two complementary forms of contraception will reduce the risk of you becoming pregnant and are preferred. Your doctor will talk to you about different forms of contraception and help you decide what is best for you.

If you think you might be pregnant

If you think you might have become pregnant while taking mycophenolate, or within 6 weeks after your last dose, talk to your doctor immediately. It is very important that you do **NOT** stop taking mycophenolate without speaking to your doctor first. If you are a transplant patient, your transplant may be rejected if you stop taking mycophenolate. Your doctor will help you determine if you are pregnant and will advise you what to do.

Important information for MEN

Because mycophenolate can cause miscarriages and birth defects it is recommended that you and your female partner use reliable contraception, while you are taking mycophenolate and for at least 90 days after the last dose.

- talk to your doctor immediately if you think your partner might be pregnant
- do not stop taking mycophenolate without speaking to your doctor
- talk to your doctor about the risks if you intend to father a child
- talk to your doctor if you have any questions or concerns

Contraception

The limited clinical evidence available does not indicate any increased risk of malformations or miscarriage if you take mycophenolate. However, a risk cannot be completely excluded. As a precaution, it is recommended that you and your female partner use reliable contraception while you are taking mycophenolate and for at least 90 days after the last dose.

Do not donate sperm while taking mycophenolate and for at least 90 days after the last dose.

If you think your partner might be pregnant

If you think your partner might have become pregnant while you were taking mycophenolate, or within 90 days after your last dose, talk to your doctor. Your doctor will help to determine if your partner is pregnant and will advise you both what to do.

Important information for men and women

If you want to have a baby

Tell your doctor if you want to have a baby. It is very important that you do **NOT** stop taking mycophenolate without speaking to your doctor.

Do not share your medicine

This medicine has been prescribed for you only. Do not give it to other people. It may harm them, even if their symptoms are the same as yours. Return any unused medicine to your pharmacist at the end of treatment.

Do not donate blood

Do not donate blood while taking mycophenolate and for at least 6 weeks after your last dose.

Your doctor's contact details

If you have urgent questions concerning the pregnancy risks of mycophenolate, please contact your doctor at the following telephone numbers:

During opening hours	
After closing	

Reporting of side effects

Please report suspected side effects to the medicines regulator MHRA through the Yellow Card Scheme.

It is easiest and quickest to report side effects online via the Yellow Cards website - <https://yellowcard.mhra.gov.uk/> or via the Yellow Card app available from the Apple App Store or Google Play Store.