

Resepta™ (Mycophenolic acid) Gastro-Resistant Tablets

Mycophenolic Acid Guide For Patients

This document is approved by The Executive Directorate of Pharmacovigilance at Saudi Food and Drug Authority

Mycophenolate Mofetil : Risks of miscarriage and birth defects

Key points to remember

- **Mycophenolate Mofetil causes birth defects and miscarriages**
- Follow the contraceptive advice given to you by your doctor to avoid accidental pregnancy
- If you do not fully understand the information you have been given, ask your doctor to explain it again before you take Mycophenolate Mofetil
- **Do NOT stop** taking Mycophenolate Mofetil without talking to your doctor
- This medicine is only for you - do not give it to anyone else because it may be harmful to them
- If you are a woman who could become pregnant, you will need to have a pregnancy test before you start taking Mycophenolate Mofetil

If you can become pregnant, or are a man who has sex with women, your prescriber will:

- talk with you about the risks of Mycophenolate Mofetil for an unborn baby
- talk with you about how to avoid these risks with contraception (birth control) and pregnancy planning
- answer any questions you may have

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

Contents:

- 1) Is this information relevant to me?
- 2) What are the risks?
- 3) How likely is it that my unborn baby will be harmed?
- 4) What should I do?

1) Is this information relevant to me?

The following people need to be particularly aware of the risks of Mycophenolate Mofetil for an unborn baby:

- pregnant women
- any woman who could become pregnant, including girls who have entered puberty and all women who have a womb and have not passed through the menopause
- men who have sex with women (including men who have had a vasectomy) and the women they have sex with

2) What are the risks?

Mycophenolate Mofetil can cause miscarriage or birth defects (problems that happen while a baby is developing in the mother's body). If a pregnant woman is exposed to Mycophenolate Mofetil, either by taking it herself or through unprotected sex with a man taking this medicine, it could cause a miscarriage or birth defects in her child. The reason this happens is not clear.

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?

If a pregnant woman is exposed to Mycophenolate Mofetil, there is a risk that it will cause a miscarriage or birth defects in her unborn baby (see above). This risk is higher for women exposed to Mycophenolate Mofetil than for women exposed to other immunosuppressants (medicines that weaken the body's immune system), and much higher than the risk in the general population.

Studies have shown that around half (45 to 49%) of all pregnancies in women taking Mycophenolate Mofetil end in miscarriage, compared 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 Mofetil during pregnancy are born with birth defects, compared with 4 to 5% for women taking other immunosuppressants following transplantation, and 2 to 3% in the general population.

4) What should I do?

Information for women and men is presented separately – see overleaf for information for men and information for both men and women.

Important information for women

Because Mycophenolate Mofetil can cause miscarriage or birth defects:

- do not take Mycophenolate Mofetil if you are pregnant or might become pregnant unless there is no suitable alternative treatment
- you will need to have a pregnancy test before you start taking Mycophenolate Mofetil
- use effective contraception (birth control) while taking Mycophenolate Mofetil and for at least 6 weeks after your last dose
- talk to your doctor immediately if you think you could be pregnant
- do **NOT** stop taking Mycophenolate Mofetil without speaking to your doctor
- talk to your doctor if you want to become pregnant, or if you have any questions or concerns.

Pregnancy tests

If you are capable of becoming pregnant, you will need to have a pregnancy test before you start taking Mycophenolate Mofetil. Your doctor will explain the type and timing of the pregnancy tests that need to be carried out before and during treatment with Mycophenolate Mofetil. He/she will recommend two blood or urine pregnancy tests; the second test should be carried out 8 to 10 days after the first one and immediately before you start taking Mycophenolate Mofetil. Your doctor might suggest repeating these tests at certain times (e.g. if there has been a gap in the use of effective contraception). He/she 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 Mofetil and for at least 6 weeks after your last dose. If you have sex with a man, use two reliable forms of contraception at the same time. 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 Mofetil, or within 6 weeks after your last dose, talk to your doctor immediately. It is very important that you do **NOT** stop taking Mycophenolate Mofetil without speaking to your doctor first. If you are a transplant patient, your transplant may be rejected if you stop taking Mycophenolate Mofetil. Your doctor will help you determine if you are pregnant, and will advise you what to do.

Important information for men

Because Mycophenolate Mofetil can cause miscarriages and birth defects:

- use condoms while taking Mycophenolate Mofetil and for at least 90 days after your last dose to avoid Mycophenolate Mofetil being passed to your female partner
- your partner should use highly effective contraception while you are taking Mycophenolate Mofetil and for at least 90 days after your last dose
- talk to your doctor immediately if you think your partner might be pregnant
- **do NOT** stop taking Mycophenolate Mofetil without speaking to your doctor
- talk to your doctor if you intend to father a child, or if you have any questions or concerns.

Contraception

Mycophenolate Mofetil can cause miscarriages and birth defects. Mycophenolate Mofetil can be transferred through semen, so your partner must not become pregnant while you are taking Mycophenolate Mofetil. To avoid Mycophenolate Mofetil being passed to your partner during sex, use condoms while taking Mycophenolate Mofetil and for at least 90 days after your last dose (even if you've had a vasectomy).

Your partner should use highly effective contraception while you are taking Mycophenolate Mofetil and for at least 90 days after your last dose.

If you think your partner might be pregnant

If you think your partner might have become pregnant while you were taking Mycophenolate Mofetil, or within 90 days after your last dose, talk to your doctor immediately. 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 Mofetil without speaking to your doctor. Your transplant may be rejected if you stop taking Mycophenolate Mofetil.

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 Mofetil 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 Mofetil, please contact your doctor at the following telephone numbers:

During opening hours	
After closing	

For further information, see the Package Leaflet.

If you think you're having a side effect

If you think you are experiencing any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

Please also report suspected side effects via The National Pharmacovigilance Centre (NPC). By reporting side effects you can help provide more information on the safety of this medicine.

The National Pharmacovigilance Centre (NPC) at Saudi Food and Drug Authority (SFDA):

- SFDA call center: 19999
- E-mail: npc.drug@sfd.gov.sa
- Website: <http://ade.sfd.gov.sa>

For any information about this medicinal product, please contact the regional representative of the MAH:

Accord Healthcare MENA
Dubai, United Arab Emirates
E-mail: mena-pv@accord-healthcare.com

**For extra copies, please contact our scientific office:
+966 114011549.**

accord

Version 2, May 2023