Mycophenolate sodium (Myfortic®)
MYCOPHENOLATE GUIDE FOR PATIENTS
Information about risks to the unborn baby

About this Guide

This Guide, the Myfortic (mycophenolate sodium) Guide for Patients, tells you about the risks of mycophenolate for the unborn baby, and the ways to reduce these risks. If you are a girl or woman who can get pregnant, or a sexually active man, your doctor will talk with you about the risks of mycophenolate for the unborn baby. Your doctor will talk about birth control and pregnancy planning, and will answer any questions you may have on this subject. This Guide will help you to remember the information you have discussed with your doctor and you should keep it so that you can refer to it again. In addition to reading this guide, it is also important that you read the package leaflet supplied with the medicine for full information on mycophenolate.

What are the risks?

If a pregnant woman is exposed to mycophenolate, either by taking it herself or through unprotected sex with a man taking this medicine, it could harm the developing baby as mycophenolate increases the risk of miscarriage and birth defects. The exact reason this happens is not clear but the risk is greater in patients taking mycophenolate than in transplant patients taking other immunosuppressants, and much greater than the risk in the general population.

Studies have shown that around half (45 to 49%) of all pregnancies in women taking mycophenolate end in miscarriage, compared with 12 to 33% in solid organ transplant patients treated with other immunosuppressants. Around a quarter (23 to 27%) of babies born to mothers taking mycophenolate during pregnancy are born with birth defects, compared with 4 to 5% in transplant patients treated with other immunosuppressants, and 2 to 3% in the overall population.

The birth defects that can occur include abnormalities of the ear, eye and face, congenital heart diseases, abnormalities of the fingers, kidney and oesophagus (part of the digestive tract connecting the mouth with the stomach). Congenital disorders of the nervous system such as spina bifida have also been observed.

Mycophenolate must therefore not be used in women who are pregnant or might become pregnant unless there is no suitable alternative treatment to prevent transplant rejection. Please talk to your doctor for more advice and information.

Who is at risk?

The following patients need to be particularly aware of the risks of mycophenolate for the unborn baby:

- Pregnant patients.
- Female patients of childbearing potential (this means any patient who could become pregnant and includes girls who have entered puberty and all women who have a uterus and have not passed through the menopause).
- Female partners of sexually active men, including men who have had a vasectomy.

Before starting or continuing treatment with mycophenolate your doctor will talk to you about the increased risks of miscarriage and birth defects that can occur and how to avoid them. This will help you understand the risks to the baby. Your doctor will also answer any questions you might have.

How to avoid the risks

To make the advice in this Guide easier to follow, specific information for women and men is presented separately.

If you are unsure about any of the information in this Guide, please talk to your doctor.

Important information for women

As mycophenolate increases the risks of miscarriage and birth defects you must:

- Be sure you are not pregnant before starting mycophenolate treatment.
- Use effective contraception during, and for 6 weeks after stopping, mycophenolate treatment.
- Talk to your doctor immediately if you think you could be pregnant.
- Tell your doctor if you plan to become pregnant.

All women capable of becoming pregnant will need to have a pregnancy test to be sure they are not pregnant before starting treatment. Your doctor will explain the type and timing of the pregnancy tests that need to be conducted before and during treatment with mycophenolate. He will recommend two blood or urine pregnancy tests; whenever feasible, a second test should be performed 8 – 10 days after the first one and immediately before starting therapy with mycophenolate. 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 will discuss with you the results of all pregnancy tests.

To be sure you do not become pregnant during treatment you will need to use effective contraception while you are taking mycophenolate and for 6 weeks after taking the last dose. Two reliable forms of contraception should be used at the same time, unless abstinence is the chosen method of contraception. Your doctor will talk to you about different contraceptive methods and help you decide what is most suitable for you.

If you think you might be pregnant when you are taking mycophenolate, or within 6 weeks after stopping treatment with mycophenolate, please talk to your doctor immediately. It is very important that you do NOT stop taking mycophenolate without speaking to a doctor. 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

Mycophenolate increases the risks of miscarriage and birth defects. Semen contains mycophenolate, therefore as a precaution, your partner must not become pregnant while you are being treated with mycophenolate. In order to avoid mycophenolate being passed from a man to a women during sex, all sexually active men (even those who have had a vasectomy) must use condoms during treatment and for at least 90 days after the last dose of mycophenolate. Also, female partners of male patients treated with mycophenolate

should use highly effective contraception during treatment and for a total of 90 days after the last dose of mycophenolate.

Tell your doctor if you intend to father a child.

If you think your partner might have become pregnant when you have been taking mycophenolate, or within 90 days after you have stopped taking mycophenolate, please talk to your doctor immediately. It is very important that you do NOT stop taking mycophenolate without speaking to a doctor. If you are a transplant patient, your transplant may be rejected if you stop taking mycophenolate. Your doctor will help you determine if your partner is pregnant, and will advise you both what to do.

You must not donate sperm during treatment with mycophenolate and for 90 days after stopping treatment.

Important information for all patients

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.

You must not donate blood during treatment with mycophenolate and for 6 weeks after stopping treatment.

In case of urgent questions concerning the pregnancy risks of Myfortic (mycophenolate sodium), please contact your doctor at the following telephone numbers:

During opening hours	
After closing	

Key points to remember

- **Mycophenolate causes birth defects and miscarriage**
- If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment
- Men and women must follow the contraceptive advice given to them by their doctor
- If you do not fully understand the information you have been given, please ask your doctor to explain it again before you take mycophenolate
- Do NOT stop taking mycophenolate without talking to your doctor
- This medicine is just for you - do not give it to other people because it may be harmful to them

Suspected adverse reactions and medication errors associated with the use of Myfortic should be reported to: Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1368, MALTA or at: www.medicinesauthority.gov.mt/adrportal

Alternatively at: Novartis Pharma Services Inc. Representative Office Malta by phone on 21222872

Marketing Authorisation Holder: Novartis Pharmaceuticals UK Ltd, Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom.

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