Myfenax

(MYCOPHENOLATE MOFETIL)

Guide for patients

INFORMATION ABOUT RISKS TO THE UNBORN BABY

Ireland
Teva Pharmaceuticals Ireland
www.teva.ie

Date of preparation: June 2018
IE/GEN/18/0005a

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About this Guide

This Guide, the Myfenax Guide for Patients, tells you about the risks of mycophenolate for the unborn baby, and the ways to reduce these risks. If you are treated with products containing mycophenolate and can get pregnant, 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 (and also available at www.hpra.ie) for full information on mycophenolate.

What are the risks?

Mycophenolate has an increased the risk of miscarriage and birth defects. The exact reason why this happens is not clear, but the risk is greater in pregnant patients taking mycophenolate than in those 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.

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The birth defects that can occur include abnormalities of the ear, eye and face (cleft lip/palate), abnormalities of the heart and abnormalities of the fingers, kidney and oesophagus (part of the digestive tract connecting the mouth to the stomach). Birth defects affecting the nervous system such as spina bifida (where the bones of the spine are not properly developed) 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).

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 before starting treatment to be sure they are not pregnant. Your doctor will explain the type and timing of the pregnancy tests that need to be conducted before and during treatment with mycophenolate.

Your doctor will recommend two blood or urine pregnancy tests; the 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). Your doctor 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. 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 is preferred. 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.

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Important information for men

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 or your female partner use reliable contraception during treatment and for a total of 90 days after the last dose of mycophenolate.

Talk to your doctor about the risks 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. 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 Myfenax, please contact your doctor at the following telephone numbers:

opening hours	after hours

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 treated with mycophenolate 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.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet for Myfenax.

Any suspected adverse reactions to Myfenax can be reported to Teva directly via email to safety.ireland@teva.ie or by telephone to 051 321538.

You can also report side effects directly via the national reporting system:
HPRA Pharmacovigilance, Earlsfort Terrace, Dublin, Ireland.
Tel 01 6764971; Fax 01 6762517;
Email: medsafety@hpra.ie; Website: www.hpra.ie

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