

# **GUIDE FOR PATIENTS CELLCEPT(MYCOPHENOLATE MOFETIL) INFORMATION ABOUT RISKS TO THE UNBORN BABY**

## **ABOUT THIS GUIDE**

This Guide, the CellCept (mycophenolate mofetil) 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 CellCept or other 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 thus 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?**

Mycophenolate has an increased 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 those 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).

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). 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. 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 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 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 CellCept, please contact your doctor at the following telephone numbers:

<b>During opening hours</b>	
<b>After closing</b>	

## **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 might be harmful to them**

## CALL FOR REPORTING

- Tell your doctor, nurse or pharmacist about any side effect you experience, bothers you or that does not go away. This includes any possible side effects not listed in the package leaflet. The side effects listed in this brochure are not all of the possible side effects that you could experience with CellCept.
- Talk to your doctor, nurse or pharmacist if you have any questions, problems or for more information.
- You can also report side effects in accordance with your country's national spontaneous reporting system directly that is provided below. By reporting side effects you can help provide more information on the safety of this medicine.
- Adverse reactions should also be reported to Roche Medical Information at Company contact point below.
- In case of any adverse events – including any possible side effects not listed in the leaflet – or product complaints associated with the use of Cellcept, please talk to the HCP or report the details in accordance with the national requirements via the national spontaneous reporting systems to:



The National Pharmacovigilance Centre  
Land Line: 19999.  
Fax: +966112057662  
Email: [npc.drug@sFDA.gov.sa](mailto:npc.drug@sFDA.gov.sa)



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This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA)