



HCP Guide

Important Safety Information

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

Mofecon

mycophenolate mofetil

version 01, october 16, 2024





Mofecon

mycophenolate mofetil

INTRODUCTION

This Guide, the Mofecon Guide for Healthcare Providers, has been designed to highlight the risks associated with exposure to mycophenolate during pregnancy, as well as the measures that should be taken to mitigate them. It will facilitate your discussion with the patient and will help you to address any questions or concerns the patient may have.

The purpose of this Guide is to minimize the number of pregnancies during treatment with this teratogenic medicinal product.

Although this Guide presents important information concerning the adverse pregnancy outcomes associated with mycophenolate, please consult the Mofecon Summary of Product Characteristics (SPC) for full information on mycophenolate.

It is advised to be read carefully before prescribing or dispensing or administering the product.

The teratogenic risks of mycophenolate




Mycophenolate is a powerful teratogen associated with an increased rate of spontaneous abortion and congenital malformation compared with other immunosuppressants. No specific mechanism of teratogenicity and mutagenicity has been identified. However, preclinical tests showed fetal resorptions and malformations in rats and rabbits in the absence of maternal toxicity. Two genotoxicity assays indicated that mycophenolate has the potential to cause chromosomal instability at severely cytotoxic dose levels.

A review of cumulative data found that around **45 to 49%** of pregnancies in women exposed to mycophenolate resulted in spontaneous abortion, compared with reported frequencies of **12 to 33%** in solid organ transplant patients treated with other immunosuppressants. The reported incidence of malformations in the offspring of mothers exposed to mycophenolate during pregnancy is **23 to 27%** compared with **4 to 5%** in transplant patients treated with other immunosuppressants, and **2 to 3%** in the overall population.

The teratogenic risks of mycophenolate

Malformations associated with mycophenolate have included abnormalities of the ear, eye and face, congenital heart disease including septal defects, polydactyly or syndactyly, tracheo-oesophageal malformations such as oesophageal atresia, effects on the nervous system such as spina bifida, and renal abnormalities.

Patients at risk of adverse pregnancy outcomes following exposure to mycophenolate include:

-  Pregnant patients.
-  All female patients of childbearing potential (i.e. girls who have entered puberty and all women who have a uterus and have not passed through menopause).
-  Female partners of sexually active men (including vasectomised men) treated with mycophenolate.

Patient counseling

Before initiating or continuing treatment with mycophenolate, female and male patients must be educated about the increased risks of spontaneous abortion and congenital malformations associated with exposure to mycophenolate. You should ensure that women and men taking mycophenolate understand the risk of harm to the foetus, the need for effective contraception, and the need to immediately consult their physician if there is a possibility of pregnancy. The information you share in this discussion will be supported by the Mofecon Guide for Patients and the Package Leaflet.

In particular, you should:

- Counsel patients at risk to make sure they understand the risks and the measures required to minimize them.
- Provide female and male patients at risk with the Mofecon Guide for Patients, and address any questions or concerns they might have.

Patient counseling

- ✔ Explain the importance, methods and timing of pregnancy tests prior and during treatment with mycophenolate.
- ✔ Provide counseling on the use of effective contraception prior to and during the entire duration of treatment with mycophenolate and for **6 weeks** (female patients) or **90 days** (male patients) after they stop taking mycophenolate.
- ✔ Advise patients using mycophenolate that they must let you know in advance if they are considering becoming pregnant or fathering a child so that you can discuss possible treatment alternatives with them.
- ✔ Advise patients treated with mycophenolate not to donate blood during or for **6 weeks** after stopping treatment.
- ✔ Advise patients that this medicine is for their own personal use, they should not give it to anyone else and should return any unused medicine to their pharmacist at the end of treatment.

Pregnancy testing

Mycophenolate must not be used during pregnancy unless there is no suitable alternative to prevent transplant rejection.

Before starting treatment with mycophenolate, women of child bearing potential should have a pregnancy test in order to exclude unintended exposure of the embryo to mycophenolate. Two serum or urine pregnancy tests with a sensitivity of at least **25 mIU/mL** are recommended; the second test should be performed **8 – 10 days** after the first one and immediately before starting mycophenolate mofetil. Pregnancy tests should be repeated as clinically required (e.g. after any gap in contraception is reported). Results of all pregnancy tests should be discussed with the patient. Patients should be instructed to consult their physician immediately should pregnancy occur.

Contraceptive requirements

Mycophenolate is contraindicated in women of childbearing potential who are not using highly effective contraception. Because of the teratogenic potential of mycophenolate, women of childbearing potential should use **two reliable forms** of contraception simultaneously before starting mycophenolate therapy, during therapy, and for **six weeks** after stopping the therapy; unless abstinence is the chosen method of contraception.

Sexually active men are recommended to use condoms during treatment and for at least **90 days** after cessation of treatment. Condom use applies for both reproductively competent and vasectomized men, because the risks associated with the transfer of seminal fluid also apply to men who have had a vasectomy. In addition, female partners of male patients treated with mycophenolate are recommended to use highly effective contraception during treatment and for a total of **90 days** after the last dose of mycophenolate.



**What to do if
pregnancy
occurs!**

Patients must consult their physician immediately should pregnancy occur during treatment with mycophenolate or within **6 weeks** after the last dose (within **90 days** in case of paternal exposure). It is very important that the patient does not stop mycophenolate without speaking to a physician as transplant patients may risk graft loss.

The correct course of action following exposure to mycophenolate during pregnancy should be based on an assessment of the individual patient's benefit-risk, and determined on a case by case basis through a discussion between the treating physician and the patient.



If you need additional hard copies of the Patient or HCP Guides or should report any case of exposure to Mofecon during pregnancy (regardless of the outcome) contact:

*** Saudi Food and Drug Authority
Pharmacovigilance and Drug Safety Center (NPC)**

Email: npc.drug@sfd.gov.sa

Toll Free Number: 19999

Fax: +966 11 2057662

Website: <https://ade.sfd.gov.sa/>

Local Safety Responsible.

Enmaeyat Pharmaceutical Industry
Riyadh 11361, Sudair City for Industry & Business

Mobile: +996500323000

Email: a.beshbeshy@enmaeyat.com.sa

Mofecon

mycophenolate mofetil
