11-March-2018

CellCept® (mycophenolate mofetil (MMF)/mycophenolic acid amended recommendations for contraception

Dear Healthcare Professional,

Roche Products Saudi Arabia (RPSA) in agreement with the Saudi Food and Drug Authority would like to inform you of the following:

Summary

- The available clinical evidence does not indicate an increased risk of malformations or miscarriage in pregnancies where the father was taking mycophenolate medicines. However, MMF and MPA are genotoxic and a risk cannot be fully excluded.
- For male patients, it is recommended that **the patients or their female partner** use reliable contraception during treatment and for at least 90 days after stopping treatment.
- The risk for women is unchanged. Mycophenolate medicines remain contraindicated in women of child bearing potential who are not using reliable contraception. These medicines are also contraindicated in pregnant women unless there are no suitable alternatives to prevent transplant rejection.
- For female patients of child bearing potential, **two reliable forms of contraception should be used simultaneously** before starting the therapy, during and for 6 weeks after stopping treatment.

Background on the safety concern

Mycophenolate, used to prevent transplant rejection, is a major human teratogen known to cause miscarriages and congenital malformation when used in pregnant women. Between 45% and 49% of cases of exposure to mycophenolate in the womb result in miscarriage, and between 23% and 27% result in malformations.

Mycophenolate medicines – both mycophenolate mofetil (MMF)[1] or mycophenolic acid (MPA) – are therefore contraindicated in women of child bearing potential not using effective contraception. Mycophenolate is also contraindicated in pregnant women unless there are no suitable alternatives to prevent transplant rejection. In addition, negative pregnancy tests are required before starting treatment (as described in the product information for these medicines).

Although the amount of mycophenolate present in semen has not been determined, calculations based on animal data show that the maximum amount of mycophenolate that could potentially be transferred to a woman is low and is unlikely to have any effect. However, mycophenolate has been shown to be genotoxic in animal studies at concentrations higher than the human therapeutic exposure levels, and the risk of genotoxic effects on sperm cells can therefore not be completely excluded.

it is recommended that sexually active male patients or their female partners should use reliable contraception during treatment and for at least 90 days after stopping mycophenolate.

[1] MMF is a pro-drug of MPA

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شركة روش برودكتس العربية السعودية المحدودة
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مكتب رقم ٥ و ٦ لابريستيج مول
طريق الملك عبدالعزيز - حي الشاطئ
جدة - المملكة العربية السعودية
رقم السجل التجاري : ٤٠٣٠٢٩٣٧٠٦
هاتف : ٢١١٤٦٠٠ ١٢ ٩٦٦+
فاكس : ٢١١٤٧٠٠ ١٢ ٩٦٦+

The risks for women are unchanged. Women of childbearing potential must use **two reliable forms of contraception simultaneously** before starting, during, and for 6 weeks after stopping treatment with mycophenolate unless abstinence is the chosen method of contraception.

Call for reporting

Please report any suspected adverse reactions associated with the use of Cellcept® mycophenolate mofetil in accordance with the national requirements via the national spontaneous reporting system, to:

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Direct Tel. +966 12211 4618
Mobile: +966 5678 44 692
Email: jeddah.drug_safety@roche.com
Local Safety Responsible: Hassan.linjawi@roche.com
www.roche.com

The National Pharmacovigilance and Drug Safety Centre (NPC)
Land Line: 19999.
Website: https://ade.sfda.gov.sa/
Email: npc.drug@sfda.gov.sa
Fax: +96612057662.

Yours Sincerely,

Hassan Linjawi	Tamer Elmahallawy	Faisal Al-Samran
QPPV/Local Safety Responsible	Medical Director	Regulatory Director

11-Mar-18

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