NOVARTIS

Our ref :

Date : 27/03/2018

اشارتنا : ٠٠١٧١٩

التاريخ : ١٨٠٠٣٠٠٩٣
١٠ / رجب / ١٤٣٩هـ

Myfortic (MYCOPHENOLATE SODIUM): amended recommendations for contraception

Dear Healthcare Professional,

In agreement with the Saudi Food and Drug Authority (SFDA), Novartis 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 Myfortic 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 form of contraception** must be used before, during and for 6 weeks after stopping treatment; unless abstinence is the chosen method of contraception.

Background on the safety concern

Mycophenolate, is indicated in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in adult patients receiving allogeneic renal transplants. It 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.

Myfortic is 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, two negative serum or urine pregnancy test with a sensitivity at least 25 miU/ml. The second test should be performed 8-10 days after the first one and immediately before starting Mycophenolate. Repeat pregnancy tests should be performed during routine follow-up visits.

Patient should be instructed to consult their physician immediately should pregnancy occur.

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مكتب شركة نوفارتس كونسلتنغ إي جي المكتب العلمي
ترخيص وزارة التجارة رقم ٣

الرياض
ص.ب :١٦٠٣٢
الرياض : ١١٤٦٤
تلفون : ٨٨٨٢ ٤٦٥
تليفاكس : ٨١٢٧ ٤٦٤

جدة
ص.ب : ٨٦٤٠
جدة : ٢١٤٩٢
تلفون : ٥٦٦٦ ٦٦٩
تليفاكس: ٣٥٣٤ ٦٦٣

الدمام
ص.ب : ٦٥٠٣
الدمام : ٣١٤٥٢
تلفون :٣١٧٤ ٨٣٤
تليفاكس : ٤٢٠٠ ٨٣٤

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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 now 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.

The previous recommendation that male patients should use condoms in addition to their female partners using a highly effective contraception has now been removed from the product information as this does not reflect the level of risk.

The risks for women are unchanged. Women of childbearing potential must use **two forms of reliable contraception** 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 mycophenolate in accordance with the national requirements via the national spontaneous reporting system, to:

Novartis Consulting AG, Patient Safety Department:
Saudi Arabia: P.O. Box 16032, Riyadh 11464, Tel: +966114658882
Phone: +996112658100
Mobile: 0545544426 or 0508035430
Fax: +966112658107
Email: adverse.events@novartis.com

National Pharmacovigilance and Drug Safety Center:
Toll free phone: 8002490000
Fax: +966112057662
E-mail: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa

Yours sincerely,

27/3/2013

Malak Alowais
Patient Safety Head Deputy (QPPV)
Novartis Saudi Arabia

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مكتب شركة نوفارتس كونسلتنغ إي جي المكتب العلمي
ترخيص وزارة التجارة رقم ٣

الرياض	جدة	الدمام
ص.ب :١٦٠٣٢	ص.ب : ٨٦٤٠	ص.ب : ٦٥٠٣
الرياض : ١١٤٦٤	جدة : ٢١٤٩٢	الدمام : ٣١٤٥٢
تلفون : ٨٨٨٢ ٤٦٥	تلفون : ٥٦٦٦ ٦٦٩	تلفون :٣١٧٤ ٨٣٤
تليفاكس : ٨١٢٧ ٤٦٤	تليفاكس: ٣٥٣٤ ٦٦٣	تليفاكس : ٤٢٠٠ ٨٣٤