SANDOZ A Novartis Division

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Direct Healthcare Professional Communication (DHPC)

14 December 2022

Mycophenolate mofetil, Lamucon ®, this DHPC is provided to inform HCPs about strengthened advice for pregnancy prevention when using mycophenolate mofetil.

Dear Healthcare professional,

Novartis in agreement with SFDA would like to inform you of the following:

Summary

We would like to inform you of the following facts about strengthened advice for pregnancy prevention when using mycophenolate mofetil.

Key elements included in the DHPC are:

1. The available clinical evidence does not indicate an increased risk of malformations or miscarriage in pregnancies where the father was taking mycophenolate medicines. However, mycophenolate mofetil (MMF) and mycophenolic acid (MPA) are genotoxic, and a risk cannot be fully excluded.
2. 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.
3. The risk for women is unchanged. Mycophenolate medicines remain contraindicated in women of childbearing 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.
4. For female patients of childbearing potential, at least one reliable form of contraception must be used before, during and for 6 weeks after stopping treatment. Two forms of contraception are preferred but not mandatory.

Background on the safety concern

Mycophenolate is used to prevent graft rejection in humans. Mycophenolate is strongly teratogenic and may cause miscarriage and congenital birth defects when used in pregnant women. In case of exposure in the womb, misscarriages occurs in 45% to 49% of cases and birth defects occurs in 23% to 27% of cases. Mycophenolate is contraindicated in pregnant women. Before the start of treatment, a negative pregnancy test is required (as the product information describes).
Although the amount of mycophenolate present in the seminal fluid has not been determined, calculations based on animal data have shown that the maximum amount of Mycophenolate, which can potentially be transmitted to women, is low, so effects are unlikely to occur.
However, in animal studies mycophenolate was genotoxic in concentrations above the human therapeutic level of exposure. Hence, the risk of genotoxic effects on sperm cannot be completely ruled out.

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It is recommended that sexually active male patients or their female partners, should use a reliable method of contraception for at least 90 days after cessation of treatment with mycophenolate.
For female patients of childbearing potential, at least one reliable form of contraception must be used before, during and for 6 weeks after stopping treatment. Two forms of contraception are preferred but not mandatory.
Full prescribing information including adverse drug reactions is available for mycophenolate containing medicinal products in the product information.
If you have questions or need further information on the use of mycophenolate mofetil containing medicines, please use according to the abovementioned contact addresses or according to the contact addresses in the respective product information.

The information in this letter has been approved by the Saudi Food and Drug Authority (SFDA).

Call for reporting

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

Novartis Pharma AG Patient Safety Department - Saudi Arabia -.
Toll Free Number: 8001240078
Phone: +966112658100
Fax: +966112658107
Email: adverse.events@novartis.com
Or by online: https://report.novartis.com/

Saudi Food and Drug Authority National Pharmacovigilance Center
Unified Contact Center: 19999
Email: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa

Company contact point

Should you need any further information, please do not hesitate to contact us:
Hajer Mohammed AlSaleh, Patient Safety Manager and Risk Management Plan Manager
Novartis Patient Safety - GDD,
Riyadh, Saudi Arabia
Phone (+966) 11 265 8100
Email :Hager.alsaleh@novartis.com or adverse.events@novartis.com
Or by online: www.novartis.com

This letter is not intended as a complete description of the benefits and risks related to the use of Lamucon ®. Please refer the full SPC (prescribing information).

Sincerely,

Hajer Alsaleh

Country Patient Safety Manager / Novartis QPPV

Alsaleh Hager

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