4. Reason for contraception failure (only if the answer to question 3c is "Yes")

A. Did the patient tell you why he/she had unprotected sexual intercourse while being treated with mycophenolate?

- ❒ Patient forgot to use contraceptives
- ❒ Patient decided not to use contraceptives due to:
- ❒ Not understanding the risks of mycophenolate
- ❒ Wanting a child
- ❒ Partner disapproval
- ❒ Side effects of contraceptive
- ❒ Health concerns
- ❒ Inconvenient to use
- ❒ Other (pleas specify): _____
  _____

- ❒ Contraceptives were used but failed (for example condom split/broke). Please specify:_____
  _____

- ❒ Patient did not explain the reason for not adopting contraception

Thank you for completing this questionnaire.

Completed by: _____
Name: _____
Signature: _____
Date: _____

Thank you for completing this questionnaire.

NOVARTIS
PHARMACEUTICALS

You can report any problem or adverse events through:

Novartis Consulting AG.
Saudi Arabia: P.O. Box 16032, Riyadh 11464 / Phone: +996112658100 / 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

Mycophenolate Sodium

myfortic™

Guided Questionnaire for Health Care Providers Reporting

Exposure During Pregnancy

NOVARTIS

Product Name: **Myfortic®**
To be completed by Novartis _____
_____

Global AER #:_____
Local Case ID: _____

You recently reported the occurrence of pregnancy in a patient or female partner of a patient treated with Myfortic (mycophenolate sodium). We would like to ask you to please complete this questionnaire, the information you provide will help us monitor and mitigate the known pregnancy risks associated with the use of Myfortic .

Answering this questionnaire is entirely voluntary and should not take more than 10 minutes of your time. Please complete the form and send it back to:

Local contact details to be added

1. Information on receipt of the Educational Materials

A. Did you receive the Myfortic Guide for Healthcare Providers on the teratogenic risks of mycophenolate?
- ❒ Yes
- ❒ No
- ❒ Do not remember

B. Did you read and understand the Myfortic Guide for Healthcare Providers on the teratogenic risks of mycophenolate?
- ❒ Yes
- ❒ No
- ❒ Do not remember

2. Information about counseling provided to the patient

A. Did you inform your patient about the risk of spontaneous abortion/birth defects associated with this drug?
- ❒ Yes
- ❒ No
- ❒ Do not remember

B. Did you provide your patient with the Myfortic Guide for Patients on the risks to the unborn baby?
- ❒ Yes
- ❒ No
- ❒ Do not remember

C. Did you advise your patient not to become pregnant / father a child while being treated with mycophenolate and for up to 6 weeks (female patients) or 90 days (male patients) thereafter?
- ❒ Yes
- ❒ No
- ❒ Do not remember

D. Did you counsel your patient about using two reliable forms of contraception simultaneously while being treated with mycophenolate and for up to 6 weeks (female patients) or 90 days (male patients) thereafter?
- ❒ Yes
- ❒ No
- ❒ Do not remember

E. Did you recommend your patient to consult you immediately in case of suspected pregnancy while being treated with mycophenolate and for up to 6 weeks (female patients) or 90 days (male patients) thereafter?
- ❒ Yes
- ❒ No
- ❒ Do not remember

3. Information on the patient's intention to become pregnant

A. Did your patient inform you of the intention to become pregnant (female patient) or father a child (male patient) whilst taking mycophenolate?
- ❒ Yes
- ❒ No
- ❒ Do not remember

B. If the answer to the previous question is "Yes", why did you decide to continue treating the patient with mycophenolate?
- ❒ Please specify _____
  _____
  _____
- ❒ Do not remember

C. Did your patient report to have had unprotected sexual intercourse at any time while being treated with mycophenolate and for up to 6 weeks (female patients) or 90 days (male patients) thereafter?
- ❒ Yes – please respond also question 4
- ❒ No – please ignore question 4
- ❒ Don't know