Guided Questionnaire for Patients reporting Mycophenolate sodium (Myfortic®) Exposure during Pregnancy

Product Name: Myfortic			
To be completed by Novartis :			
Global AER #:		Local Case ID:	

IMPORTANT

If you have not already contacted your doctor regarding the reported pregnancy please do so immediately

Following your recent report to Novartis regarding your pregnancy or your partner's pregnancy, we would like to ask you to complete this short tick-box questionnaire. Answering this questionnaire will not affect the treatment you receive from your doctor. The information you provide is confidential and nothing that identifies you will be recorded. The information you supply will help us to ensure that Myfortic (mycophenolate sodium) is used as safely as possible. Please answer all questions and send the questionnaire back to:

Novartis Pharma Services Inc., Representative Office Malta, P.O. Box 4, Marsa, MRS 1000.

By returning this questionnaire you are agreeing that Novartis can enter the anonymous information you provide onto a computer database. Thank you for taking the time to complete this questionnaire.

1. Information about you		
Are you male or female? ❑ Male ❑ Female	Was this pregnancy planned? ❑ Yes ❑ No	When did you start therapy with Myfortic ? ❑ Date:_____ ❑ Do not remember

2. Information received before starting taking Myfortic(mycophenolate sodium)			
a. Did you receive the Myfortic *Guide for Patients* about risks to the unborn baby?	❑ Yes	❑ No	❑ Do not remember
b. **Female patients only**: were you told not to become pregnant and to use effective contraception when taking Myfortic and for 6 weeks after stopping Myfortic?	❑ Yes	❑ No	❑ Do not remember

2. Information received before starting taking Myfortic(mycophenolate sodium)			
c. **Male patients only**: were you told not to father a child and to use effective contraception when taking Myfortic and for 90 days after stopping Myfortic?	❑ Yes	❑ No	❑ Do not remember
d. Did you receive information about what contraception you should use?	❑ Yes	❑ No	❑ Do not remember
e. If you answered yes to questions a, b, c or d, who provided the information? (please check/tick all that apply)	❑ Doctor who prescribed Myfortic ❑ Gynaecologist ❑ Contraceptive counsellor, family planning advisor, health educator, nurse, pharmacist ❑ Other (please specify) _____ ❑ Do not remember		

3. Information about pregnancy testing and contraception (birth control)	
a. Female patients only: did you have negative pregnancy tests before you started taking Myfortic?	❑ Yes, one negative test ❑ Yes, two negative tests ❑ No ❑ Do not remember
b. Did you use two forms of contraception when you were taking Myfortic and for 6 weeks (for female patients) or 90 days (for male patients) after stopping Myfortic?	❑ Yes ❑ No ❑ Do not remember
c. If you used contraception, what types of contraception did you use? Please check/tick all that apply	❑ Intrauterine device (IUD) or coil ❑ Hormonal (Progestin) IUD ❑ Hormones (birth control/contraceptive pills, hormonal patches, shots or implants) ❑ Sterilization (tubal sterilization, hysterectomy, vasectomy) ❑ Condom with spermicide ❑ Condom without spermicide ❑ Diaphragm with spermicide ❑ Diaphragm without spermicide

3. Information about pregnancy testing and contraception (birth control)	
	❑ Abstinence ❑ Cervical cap or shield ❑ Sponge ❑ Withdrawal ❑ Other (please specify) _____

4. Information on sexual intercourse without effective contraception (birth control)	
a. Did you or your partner have sexual intercourse without effective contraception at any time during or within 6 weeks (for female patients) or 90 days (for male patients) after the use of Myfortic?	❑ Yes – please respond also to question 5 ❑ No – please ignore question 5

5. Reason contraception (birth control) was not used or was not effective	
a. Please check/tick all that apply	❑ Forgot to use contraception ❑ Contraception failed (for example condom split/broke) ❑ Stopped using contraception. Please explain why:_____ _____ ❑ Did not know contraception should be used ❑ Other (please specify) _____

Thank you for completing this questionnaire.

Completed by:			
Initials only:		Date:	

Suspected adverse reactions and medication errors associated with the use of Myfortic should be reported to: Malta Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, or at: www.medicinesauthority.gov.mt/adrportal.

Alternatively at: Novartis Pharma Services Inc., Representative Office, Malta by phone on 21222872