

RMS19486 / 999 / (3) 12345

Mrs A Tennant
Chief Pharmacist
Pharmacy
New Cross Hospital
Wolverhampton Road
Heath Town
WOLVERHAMPTON WV10 0QP

October 2019

Dear Mrs Tennant,

IMPORTANT SAFETY INFORMATION – MYCOPHENOLATE

RISK OF TERATOGENICITY

Mycophenolate is used in combination with ciclosporin and corticosteroids for the prevention of acute transplant rejection.

Mycophenolate is a powerful teratogen associated with an increased rate of spontaneous abortion and congenital malformation compared with other immunosuppressants.

To highlight the risks to babies associated with exposure to mycophenolate during pregnancy and to minimise the number of pregnancies during treatment with this teratogenic medicinal product, risk minimisation materials have been formally approved by the regulatory authority (MHRA).

1. Guide for Healthcare Providers – risk of teratogenicity
2. Patient Guide – Mycophenolate: risks of miscarriage and birth defects

Risk minimisation documents are being made available to increase awareness and improve the monitoring and management of these risks.

The materials are being provided by the group of generic companies listed below, who are Marketing Authorisation holders for medicines containing mycophenolate. Electronic copies of the materials are available from company websites and/or the electronic Medicines Compendium (eMC) <https://www.medicines.org.uk/emc>. If you require additional information, please contact the individual company.

Reporting of side effects

Please continue to report suspected side effects to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected side effects that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected side effects associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report side effects online via the Yellow Cards website - <https://yellowcard.mhra.gov.uk/> or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary); by emailing yellowcard@mhra.gov.uk; at the back of the British National Formulary (BNF); by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789; or by downloading and printing a form from the Yellow Card website.

Yours sincerely,



Paul Fleming
Technical Director



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Company	Medical Information contact details
Accord-UK Ltd and Accord Healthcare Limited	medinfo@accord-healthcare.com Telephone: 01271 385 257
Ascend Laboratories (UK) Limited	pvglobal@alkem.com Telephone: 0800 0470073
Morningside Healthcare Limited	medicalenquiry@morningsidehealthcare.com Telephone: 0345 4592137
Mylan	Info.uk@mylan.co.uk Telephone: 01748 828 888
Members of the Sandoz group including Sandoz Ltd	Sandozgb@EU.propharmagroup.com Telephone: 01276 698 101
Teva B.V.	medinfo@tevauk.com Telephone: 0207 540 7117
Tillomed Laboratories Ltd	medical.information@tillomed.co.uk Telephone: 01480 402 400
Wockhardt UK Limited	drug.safety@wockhardt.co.uk Telephone: 01978 669 272

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