SHARED CARE ARRANGEMENT AND PRESCRIBING INFORMATION FOR MYCOPHENOLATE MOFETIL (RENAL ADULT)

N.B. This document should be read in conjunction with the current Summary of Product Characteristics (SmPC).

Patient safety is paramount. The prescriber who prescribes the medicine legally assumes clinical responsibility for the drug and the consequences of its use.

GENERIC AND BRAND NAME (formulations and strength)

Name: Mycophenolate Mofetil (Cellcept® or Myfenax®)

Formulation: Capsule, Tablet and Suspension

Strength: 250mg Capsule, 500mg Tablet, 200mg per 1mL Suspension

N.B. Mycophenolate Mofetil must be prescribed by brand name, and it is preferred that the one brand is prescribed consistently. Tablets and suspension can be used interchangeably if required.

STATUS OF MEDICINE

Licence status: Licensed (Prophylaxis of Rejection in Renal Transplantation)

Formulary status: Formulary

Black triangle medicine: NO

Risk minimisation materials: YES – Cellcept® 500mg Tablets https://www.medicines.org.uk/emc/product/1103/rmms but will apply to other Mycophenolate Mofetil preparations.

CONDITION(S) TO BE TREATED

Mycophenolate Mofetil is indicated for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal transplants.

TYPICAL DOSAGE REGIME	
Licensed dose	See Renal Specialist for advice
Route of administration	Oral
Recommended starting dose	See Renal Specialist for advice
Titration dose/increment	See Renal Specialist for advice
Maximum dose	See Renal Specialist for advice
Situations requiring dose adjustment	See Renal Specialist for advice
Duration of treatment	See Renal Specialist for advice

RESPONSIBILITY OF ACUTE CARE/SPECIALIST SERVICE

1. **Baseline:**
   Full Blood Count (FBC); U&Es, Creatinine, Blood Pressure and Lipids.
2. Copy of results to be sent to GP.
3. Exclude pregnancy before starting therapy:
   - Give advice on contraception and tell patient to use contraception for at least 6 weeks after discontinuation of treatment.
   - Advise patient to contact their physician immediately should pregnancy occur.
4. Initiation of therapy and recommendations for dose increments. This will be controlled by the Renal Unit.
5. The Renal Unit has primary responsibility for monitoring clinical response to treatment according to the schedule below.
   - Weekly full blood counts for 4 weeks then fortnightly for 2 months then monthly for one year then 3 monthly thereafter. If stable after 2 years go to 6 monthly monitoring. Also U&E (incl. creatinine), LFTs and blood pressure every 3 months.

RESPONSIBILITY OF PRIMARY CARE

To preserve vital venous access, monitoring will be done by the renal service at ARI unless otherwise notified or the patient develops an intercurrent illness which would require bloods to be taken in primary care.

A Practice agreeing to prescribe Mycophenolate Mofetil should:

1. Prescribe medication under the guidance of the Renal Consultant.
2. Ensure the GP is aware that the drug can cause:
   - Leucopenia and Thrombocytopenia
   - Infection
   - Bone marrow depression
   - Increased risk of malignancy – lymphomas and skin cancer
   - Raised blood pressure and dyslipidaemia
   - Patients should be asked about the presence of sore throat, abnormal bruising or bleeding at each visit.
3. Ensure that the relevant monitoring requirements have been undertaken at the correct frequency above.
4. Ensure.when the patient has an intercurrent illness FBC, U+E and LFTs are done and make sure abnormal results are acted upon promptly.
5. Only continue to prescribe medication if it is being satisfactorily monitored.
6. Contact the Renal Unit/Consultant/On Call Registrar in the event of a drug reaction, monitoring abnormality, or if you are concerned in any way regarding the current treatment regime.
7. Be alert for any of the known adverse reactions.

CARE WHICH IS THE RESPONSIBILITY OF THE PRESCRIBING CLINICIAN

1. Undertake prescribing of medication (by brand name) under guidance of consultant.
2. Check before prescribing each instalment of medication that the monitoring is up to date and that results are within the normal range.
3. Ensure no interacting medications are prescribed in primary care.

4. Monitor for concordance with therapy.
5. Report any adverse events to consultant and the MHRA using the Yellow Card System.
6. If an intercurrent illness occurs, when writing laboratory request forms always include details of the patient's medication.
7. If bloods are taken due to intercurrent illness, ensure they are monitored and contact hospital consultant to advise if results are out with range.
8. A single pneumococcal polysaccharide vaccine and annual influenza vaccine should be given.

N.B. In addition to absolute values for haematological or biochemical indices a rapid change or a consistent upward/downward trend in any value should prompt caution and extra vigilance.

N.B. If something unexpected occurs contact Renal Unit, On Call Registrar or Consultant. Notify the consultant if the drug is stopped.

RESPONSIBILITY OF OTHER HEALTHCARE PROFESSIONALS

N/A

RESPONSIBILITY OF THE PATIENT

- Take medication regularly as directed by the specialist/doctor.
- Attend hospital and GP clinic appointments as requested by specialist/GP practice. Failure to attend appointments may result in medication being reviewed/stopped.
- Report any adverse effects/illness to the specialist/GP and present rapidly to specialist/GP should their condition significantly worsen.
- To minimise the risk of skin cancer, exposure to sunlight and Ultra Violet light should be limited by wearing protective clothing and using sunscreen with a high protection factor.

PRESCRIBING INFORMATION

For specific product information consult the current summary of product characteristics (http://emc.medicines.org.uk/), the BNF/BNF for Children (https://www.medicinescomplete.com/mc/index.htm)

CONTRAINDICATIONS

Avoid in patients with hypersensitivity to mycophenolate mofetil, mycophenolic acid or to any of the excipients.

PREGNANCY

Discuss with Renal Consultant. Contraindicated in pregnancy. See: https://www.medicines.org.uk/emc/product/1102/smpc and https://www.medicines.org.uk/emc/rmm-directory/M and https://www.medicines.org.uk/emc/rmm/1228/Document. Advise the patient to contact their physician immediately should pregnancy occur.

BREAST-FEEDING

Discuss with Aberdeen Maternity Hospital. Manufacturer advises avoid.

COMMON SIDE EFFECTS AND THEIR MANAGEMENT

- Candidiasis
- Vomiting
- Diarrhoea
- Nausea
- Abdominal pain
- GI ulceration.

Abnormal Monitoring Results	Action To Be Taken
• **WBC** < 4.0 x 10^9/L	Discuss with Renal Unit/Registrar on call or Consultant
• **Neutrophils** < 2.0 x 10^9/L	Discuss with Renal Unit/Registrar on call or Consultant
• **Platelets** < 150x10^9/L	Discuss with Renal Unit/Registrar on call or Consultant
• **> 2-fold rise in ALT or Alk Phos** (from upper limit of reference range) • Other significantly deranged LFT results	Discuss with Renal Unit/Registrar on call or Consultant
• MCV>105fl	Investigate and if B12 or folate low start appropriate supplementation
• Abnormal bruising, sore throat, rash, oral ulceration	Check FBC. Discuss with Renal Unit/Registrar on call or Consultant
• Unexplained fever	Discuss with Renal Unit/Registrar on call or Consultant
• Malignancies	Discuss with Renal Unit/Registrar on call or Consultant
• Haematemesis, coffee ground vomit or melaena	Discuss with Renal Unit/Registrar on call or Consultant

COMMON DRUG INTERACTIONS (for a full list see SmPC)

- Live vaccines should be avoided in patients taking mycophenolate mofetil.
- Some important interactions to consider include the following:
  - Aciclovir administered concurrently with mycophenolate mofetil increases blood concentration levels of each. This interaction only significant in renal impairment.
  - Mycophenolate mofetil absorption is reduced by antacids, colestyramine or iron.
- Avoid concomitant administration of drugs that increase the risk of agranulocytosis, e.g. clozapine.
- Do not give concomitantly with azathioprine as combination has not been studied.

- To minimise the risk of skin cancer, exposure to sunlight and ultra violet light should be limited by wearing protective clothing and using sunscreen with a high protection factor.

ADVERSE DRUG REPORTING

If an adverse reaction should occur, inform relevant medical practitioner as soon as possible.

Report to the MHRA using the Yellow Card System https://yellowcard.mhra.gov.uk/

REFERENCES

https://www.medicines.org.uk/emc/product/1102/smpc
https://www.medicines.org.uk/emc/rmm/1228/Document
https://www.medicines.org.uk/emc/rmm/1228/Document

ACUTE CARE/SPECIALIST SERVICE CONTACT INFORMATION

In the event of concern being raised, the primary care practitioner should contact the referring consultant via the hospital switchboard, via their secretary, by e-mail or letter, whichever is more appropriate. If the concern is urgent, and out of hours advice is required, the on call Renal Registrar may be contacted via switchboard.

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