RENAL TRANSPLANT PATIENTS ONLY

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

Clinicians must ensure they are referring to the correct SCA for specialty/situation.

This SCA is for RENAL TRANSPLANT PATIENTS ONLY. Some content and recommendations may differ from the SCA for patients receiving this treatment for conditions other than renal transplant. This is due to the specialist service clinical recommendations and monitoring requirements for managing transplant patients.

Note: 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 NAME (formulations and strength)

Name: Mycophenolate Mofetil

Formulation: Capsule, Tablet and Suspension

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

STATUS OF MEDICINE

Licence status: Licensed

Formulary status: Formulary

Black triangle medicine: No

Risk minimisation materials (RMM): 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 UNDER THIS SCA

RENAL TRANSPLANT: Mycophenolate Mofetil is indicated for the prophylaxis of acute transplant rejection in patients receiving allogenic 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

- Baseline:
  - Full Blood Count (FBC), Liver Function Tests (LFTs), and Urea and Electrolytes (U&Es)
  - Lipids
  - Blood Pressure (BP)
- Copy of results to be sent to primary care.
- 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 the patient to contact their physician immediately should pregnancy occur
- Request initiation of therapy, confirming dose to be prescribed and recommendations for dose increments to Primary Care.
- Monitoring clinical response to treatment and advise on final dose required for the patient.
- Ongoing Blood monitoring – the Renal service has the primary responsibility for **RENAL TRANSPLANT** patients blood monitoring and review of results.

  This will follow a normal schedule of:
  - full blood counts, U+E, creatinine, blood pressure and LFTs three times per week for first two weeks after discharge,
  - weekly until week 8,
  - alternate weeks until week 12 to 16 (depending on graft function),
  - monthly until end of six months,
  - two to three monthly until end of first year,
  - and three to six monthly during year two and beyond if stable with satisfactory graft function,
  - lipids monitored every 12 months.

  If any individual monitoring is to be performed out with this schedule the renal service should advise primary care accordingly, this is necessary to ensure compliance with monitoring schedules prior to prescribing.

- Patients should be asked about the presence of sore throat, rash or abnormal bruising at each visit.
- Pneumococcal polysaccharide vaccine (PPV), COVID-19 vaccine and annual influenza vaccine should be given as per Joint Committee of Vaccination and Immunisation (JCVI)/The Green Book recommendations. Shingles vaccine should be given to those individuals who are severely immunocompromised, or anticipating immunosuppressive therapy, and eligible in line with JCVI/The Green Book recommendations and Scottish Government vaccination programme. Patients should be referred by specialist services to receive these vaccines in accordance with local protocol.

RESPONSIBILITIES OF PRIMARY CARE/PRESCRIBING CLINICIAN

To preserve vital venous access, blood monitoring for RENAL TRANSPLANT patients will be done by the renal specialist service 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 for **RENAL TRANSPLANT** should:

- Prescribe medication under the guidance of the Renal Consultant.
  Checking before prescribing each instalment of medication that the monitoring is up to date and that results are within a satisfactory range.
- Ensure that the relevant monitoring requirements have been undertaken at the correct frequency (see information under responsibility of Acute care /specialist service).

- Only continue to prescribe medication if it is being satisfactorily monitored. Noting medication should not be stopped without first discussing with the renal consultant, specialist service.
- 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.
- Ensure when the patient has an intercurrent illness FBC, U+E and LFTs are done and make sure abnormal results are acted upon promptly. If an intercurrent illness occurs, when completing laboratory request always include details of the patient's medication.
- If bloods are taken due to intercurrent illness, ensure they are monitored and contact renal consultant to advise if results are out with range (see Abnormal Monitoring section).
- 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.
- Be alert for any of the known adverse reactions.
- Ensure no interacting medications are prescribed in primary care.
- Monitor for concordance with therapy.
- The patient should be encouraged to ensure blood tests are undertaken at the correct intervals (see information under responsibility of Acute care /specialist service)
- It is responsibility of primary care to ensure that the medication is recorded on the patient's clinical medication record. This will facilitate central searches for vaccinations in order to ensure patients receiving immunosuppressants are called by the HSCP teams for required vaccinations e.g. influenza and covid programmes.
- Report any adverse events to consultant and the MHRA using the Yellow Card System.
- Post exposure prophylaxis (PEP) should be considered in non-immune individuals if exposed to shingles or chickenpox as per The Green Book.
- If something unexpected occurs contact on call renal registrar or consultant.

MONITORING

To preserve vital venous access, blood monitoring for **RENAL TRANSPLANT** patients will be done by the renal specialist service unless otherwise notified OR the patient develops an intercurrent illness which would require bloods to be taken in primary care.

Results should be reviewed and action taken as per Abnormal Monitoring Section below.
For **RENAL TRANSPLANT** the renal specialist service will review results, for monitoring they have undertaken.

All results should also be reviewed by Primary Care routinely prior to prescribing, and if additional monitoring due to an intercurrent illness.

Note: 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.

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.

- The patient should ensure that all blood tests are taken at the correct intervals.
- 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 (minimum SPF 30).
- Be aware of need to use contraception were appropriate.

PRESCRIBING INFORMATION

For specific product information consult the current summary of product characteristics (http://emc.medicines.org.uk/), the BNF/BNF for Children BNF (British National Formulary) | NICE

CONTRAINDICATIONS

For full details please refer to the current Summary of Product Characteristics (SmPC) available at www.medicines.org.uk

- Avoid in patients with hypersensitivity to mycophenolate mofetil, mycophenolic acid or to any of the excipients.
- Women of childbearing potential who are not using highly effective contraception.

Note: Treatment should not be initiated in women of childbearing potential without providing a pregnancy test result to rule out unintended use in pregnancy.

PREGNANCY RENAL TRANSPLANT

Discuss with Renal Consultant. Mycophenolate mofetil should not be used during pregnancy unless there is no suitable alternative treatment to prevent transplant rejection.

Women on mycophenolate mofetil should be advised to seek specialist advice prior to conception as mycophenolate should be stopped and switched to another pregnancy compatible drug at least six weeks before planned conception.

BREAST-FEEDING RENAL TRANSPLANT

Discuss with Renal Consultant. Manufacturer advises to avoid.

COMMON SIDE EFFECTS

Infections and Infestations	Bacterial infection, fungal infections and viral infections. In the event of infection please do not discontinue immunosuppression without discussion with the renal consultant. It can be considered appropriate to continue these drugs in patients with minor viral and bacterial infections.
Neoplasms benign, malignant and unspecified (including cysts and polyps)	Benign neoplasm of skin, neoplasm and skin cancer. 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.
Blood and lymphatic system disorders	Anaemia, ecchymosis, leukocytosis, leucopenia, pancytopenia and thrombocytopenia

Metabolism and nutrition disorders	Acidosis, hypercholesterolemia, hyperglycaemia, hyperkalaemia, hyperlipidaemia, hypocalcaemia, hypokalaemia, hypomagnesemia, hypophosphatemia, hyperuricaemia, gout and weight decreased
Psychiatric disorders	Confusional state, depression, insomnia and anxiety
Nervous system disorders	Dizziness, headache, hypertonia, paresthesia, somnolence, tremor and convulsion
Cardiac disorders	Tachycardia
Vascular disorders	Hypertension, hypotension, venous thrombosis and vasodilatation
Respiratory, thoracic and mediastinal disorders	Cough, dyspnoea and pleural effusion
Gastrointestinal disorders	Abdominal distension, abdominal pain, colitis, constipation, decreased appetite, diarrhoea, dyspepsia, esophagitis, flatulence, gastritis, gastro-intestinal haemorrhage, gastrointestinal ulcer, gingival hyperplasia, ileus, mouth ulceration, nausea, stomatitis and vomiting
Hepatobiliary disorders	Blood alkaline phosphatase increased, blood lactate dehydrogenase increased, hepatic enzyme increased and hyperbilirubinaemia
Skin and subcutaneous tissue disorders	Acne, alopecia, rash and skin hypertrophy
Musculoskeletal and connective tissue disorders	Arthralgia and muscular weakness
Renal and urinary disorders	Blood creatinine increased, haematuria and renal impairment
General disorders	Asthenia, chills, oedema, hernia, malaise, pain and pyrexia

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 <150 x 10^9/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

Some important interactions to consider include the following:

- Aciclovir - administered concurrently with mycophenolate mofetil increases blood concentration levels of each. This interaction is only significant in renal impairment.
- Antacids, colestyramine or iron reduce absorption of mycophenolate mofetil.
- Clozapine - avoid concomitant administration of drugs that increase the risk of agranulocytosis.
- Live vaccines should be avoided. Immunosuppressants may affect the response to vaccination and vaccination during treatment may be less effective.

This information is not intended to be a complete list of interactions. For further information consider appropriate reference sources such as SmPC/Vision system.

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

www.medicines.org.uk/emc/product/1102/smpc
www.medicines.org.uk/emc/product/9294/smpc
www.medicines.org.uk/emc/rmm/1228/Document

ACUTE CARE/SPECIALIST SERVICE CONTACT INFORMATION

In the event of a 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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