SHARED CARE ARRANGEMENT AND PRESCRIBING INFORMATION FOR MYCOPHENOLATE MOFETIL (ADULTS) EXCLUDING RENAL TRANSPLANT

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

This SCA is applicable for ALL conditions/specialities EXCLUDING RENAL 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 – prophylaxis of rejection in transplantation. Off-label use in rheumatology, gastroenterology, neurology and dermatology.

Formulary status: Formulary – available for restricted use under specialist supervision.

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 UNDER THIS SCA

- Prevention of rejection following organ transplantation (excluding renal transplant).
- Mycophenolate mofetil may be used within rheumatology, gastroenterology, neurology dermatology and renal specialties and may be used for licensed and unlicensed indications including as a steroid sparing agent and general immunosuppressant.

TYPICAL DOSAGE REGIME	
Licensed dose	See Specialist service/SmPC for advice – variable according to condition being treated
Route of administration	Oral
Recommended starting dose	See Specialist service for advice – variable according to condition being treated
Titration dose/increment	See Specialist service for advice

TYPICAL DOSAGE REGIME	
Maximum dose	See Specialist service for advice
Situations requiring dose adjustment	See Specialist service for advice and Monitoring Schedule for DMARDs
Duration of treatment	See Specialist service for advice

RESPONSIBILITY OF ACUTE CARE/SPECIALIST SERVICE

- Baseline: as per Monitoring Schedule for DMARDs:
  - Full Blood Count (FBC), Liver Function Tests (LFTs), and Urea and Electrolytes (U&Es)
- Copy of baseline results to be shared with 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 patient to contact their physician immediately should pregnancy occur
- Request for initiation of therapy and recommendations for dose increments to Primary Care.
- Monitoring clinical response to treatment and advising on final dose required for the patient. Clinical decision regarding final dose required for patient.
- 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.

RESPONSIBILITY OF PRIMARY CARE/PRESCRIBING CLINICIAN

A Practice agreeing to prescribe mycophenolate mofetil should:

- Prescribe medication under the guidance of the Consultant from the relevant specialist service.
- Checking before prescribing each instalment of medication that the monitoring is up to date and that results are within a satisfactory range.
- Note: for individuals referred for vaccinations by the specialist service it is ideal to wait for vaccinations before starting immunosuppressive treatments. However this risks not controlling the autoimmune condition quickly which can negatively affect long term prognosis. Therefore specialties do not insist on a delay in starting immunosuppressive treatment to allow for vaccinations and recommend vaccinations happen as soon as possible after starting immunosuppressive treatment.
- Ensure that the relevant monitoring requirements have been undertaken at the correct frequency.
- The Practice/General Practitioner (GP) has primary responsibility for monitoring according to the Monitoring Schedule for DMARDs and review results.
- Only continue to prescribe medication if it is being satisfactorily monitored.
- 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 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 action taken as per the Monitoring Schedule for DMARDs.
- Infection - During a serious infection mycophenolate should be temporarily discontinued until the patient has recovered from the infection and is off antibiotics for 2 weeks with no recurrence of infection. (This excludes any transplant patients who should be discussed with specialist service).
  It can be considered appropriate to continue these drugs in patients with minor or uncomplicated viral infections or, if deemed clinically appropriate by the Specialist, in patients requiring long term antibiotic prophylaxis e.g. for prevention of recurrent UTIs.
- Contact the relevant specialist service 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 Consultant of appropriate specialist service.

MONITORING

Refer to the NHSG Guidelines For The Monitoring of Disease Modifying Anti-Rheumatic Drugs (DMARDs) For Healthcare Professionals.

Primary Care are responsible to ensure results are reviewed and action taken as per monitoring guidance.

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 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 detail please refer to the current Summary Product Characteristic (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.
- Severe infections - during a serious infection mycophenolate should be temporarily discontinued until the patient has recovered from the infection and is off antibiotics for 2 weeks with no recurrence of infection. (This excludes any transplant patients who should be discussed with specialist service).

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

Discuss with relevant specialist service. Mycophenolic mofetil should not be used during pregnancy. 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

Discuss with Specialist service. Manufacturer advises to avoid.

COMMON SIDE EFFECTS

Infections and Infestations	Bacterial infection, fungal infections and viral infections
Neoplasms benign, malignant and unspecified (including cysts and polyps)	Benign neoplasm of skin, neoplasm and skin cancer
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 and administration site conditions	Asthenia, chills, oedema, hernia, malaise, pain and pyrexia

Action abnormal monitoring results are per NHSG Disease Modifying Anti-Rheumatic Drugs (DMARDs) Monitoring Guidance.

The specialist service should be contacted if there are any patient specific issues or concerns regarding side effects or abnormal results.

COMMON DRUG INTERACTIONS (for a full list see SmPC)

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

- Cellcept 500mg Film-Coated Tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)

ACUTE CARE/SPECIALIST SERVICE CONTACT INFORMATION

In the event of a concern being raised, the primary care practitioner should contact the referring consultant for the appropriate specialist service 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 Registrar for the speciality may be contacted via the switchboard.

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