SHARED CARE ARRANGEMENT AND PRESCRIBING INFORMATION FOR MYCOPHENOLATE MOFETIL (ADULTS ONLY - NON-RENAL 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 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

Note: 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/hepatic transplantation. Off-label use in rheumatology, gastroenterology 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

Mycophenolic Mofetil is an immunosuppressant medication used to prevent rejection following organ transplantation. It is also used within rheumatology, gastroenterology and dermatology specialties.

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
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:
  - Full Blood Count (FBC); liver function tests.
  - LFTs; urea, U&Es; lipids, urinalysis and blood pressure (BP).
- 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.
- Initiation of therapy and recommendations for dose increments. This should remain under the control of the specialist service.
- Decision on final dose required for patient.
- A single dose of pneumococcal polysaccharide vaccine and annual influenza vaccine should be given; patients should be referred to receive these vaccines in accordance with local protocol.

RESPONSIBILITY OF PRIMARY CARE

A Practice agreeing to prescribe Mycophenolic Mofetil should:

- Prescribe medication (by brand name) under the guidance of the Consultant from the relevant specialist service.
- The General Practitioner (GP) has primary responsibility for monitoring according to the Monitoring Schedule for DMARDs
- 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 that the relevant monitoring requirements have been undertaken at the correct frequency.
- Ensure when the patient has an intercurrent illness FBC, U+E and LFTs are done and abnormal results are acted upon promptly.
- Only continue to prescribe medication if it is being satisfactorily monitored.
- 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.
- The patient should be encouraged to ensure blood tests are undertaken at the correct intervals.
- 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 annual vaccinations in order to ensure patients receiving DMARDs are called yearly by the HSCP teams for required vaccinations.

CARE WHICH IS THE RESPONSIBILITY OF THE PRESCRIBING CLINICIAN

- Prescribe medication (**by brand name**) under guidance of the relevant specialist service.
- Check before prescribing each instalment of medication that the monitoring is up to date and that results are within the normal range.
- Ensure no interacting medications are prescribed in primary care.
- Monitor for concordance with therapy.
- Report any adverse events to consultant and the MHRA using the Yellow Card System.
- If an intercurrent illness occurs, when writing laboratory request forms always include details of the patient's medication.
- If bloods are taken due to intercurrent illness, ensure they are monitored and contact hospital consultant to advise if results are out with range.
- A single dose of pneumococcal polysaccharide vaccine and annual influenza vaccine should be given; patients should be referred to receive these vaccines in accordance with local protocol.

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.

Note: If something unexpected occurs contact on call registrar or Consultant for the appropriate specialty. Notify the consultant if the drug is stopped.

MONITORING

Refer to the NHSG Guidelines For The Monitoring of Disease Modifying Anti-Rheumatic Drugs (DMARDs) For Healthcare Professionals. Results should be reviewed and action taken as per monitoring guidance.

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.
- The patient should ensure all blood tests are undertaken at the correct intervals.

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

For full detail please refer to the current Summary Product Characteristic (SmPC) available at www.medicines.org.uk

- Hypersensitivity to the active substance 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

Mycophenolic Mofetil should not be used during pregnancy unless there is no suitable alternative treatment to prevent transplant rejection. Discuss with relevant specialist service.

BREAST-FEEDING

Further discussion is required with the relevant specialist service

COMMON SIDE EFFECTS AND THEIR MANAGEMENT

Blood and lymphatic system disorders	Leucopenia, anemia, ecchymosis, leukocytosis, pancytopenia and thrombocytopenia
Metabolism and nutrition disorders	Acidosis, hypercholesterolemia, hyperlipidaemia, hyperglycaemia, anorexia, hyperuricaemia, hypocalcemia, hypokalaemia, hypomagnesaemia, hypophosphatemia, hyperuricaemia, gout and weight loss
Vascular disorders	Hypertension, hypotension, venous thrombosis and vasodilation

Gastrointestinal disorders	Nausea, vomiting, abdominal discomfort/pain, diarrhoea, gingival hyperplasia, colitis, constipation, decreased appetite, dyspepsia, esophagitis, flatulence, gastritis, GI haemorrhage, ileus, mouth ulceration and stomatitis
Skin and subcutaneous tissue disorders	Alopecia, acne, rash and skin hypertrophy
Musculoskeletal and connective tissue disorders	Arthralgia and muscle weakness
Infections and infestations	Bacterial infections, fungal infections, protozoal infections and viral infections
Neoplasms benign, malignant and unspecified (including cysts and polyps)	Benign neoplasm of skin, neoplasm and skin cancer
Psychiatric disorders	Confusional state, depression, insomnia, agitation, anxiety and abnormal thinking.
Nervous system disorders	Dizziness, headache, hypertonia, paresthesia, somnolence, tremor and convulsion
Respiratory, thoracic and mediastinal disorders	Cough, dyspnea and pleural effusion
Hepatobiliary disorders	Blood alkaline phosphatase increased, blood lactate dehydrogenase increased, hepatic enzyme increased, hepatitis, hyperbilirubinemia and jaundice
Other very common or common side effects	Tachycardia, asthenia, chills, edema, 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)

For full detail of the numerous drug interactions with Mycophenolic Mofetil please refer to the current Summary of Product Characteristics (SmPC) available at www.medicines.org.uk

- 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

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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