Mycophenolate Mofetil Shared Care Guideline For Dermatology

Consultant Details	Patient Identifier
Name: **Hospital:** **Tel:**	

Introduction

Mycophenolate Mofetil is licensed for the prevention of transplant rejection.
However, it can also be used for the treatment of:

- Systemic inflammatory diseases (e.g. SLE and vasculitis) and is also occasionally used in the treatment of inflammatory joint disease;
- Some dermatological conditions such as dermatomyositis and polymyositis; severe psoriasis, severe atopic dermatitis, blistering conditions; pyoderma gangrenosum; vasculitis and autoimmune bullous dermatoses such as pemphigus.

Although some of these uses of mycophenolate are unlicensed, it is nevertheless regularly used within the UK for this indication and accepted internationally.

Dose and administration

- Mycophenolate Mofetil is given orally.
- The usual starting dose is 1 gram daily, given in 2 divided doses (i.e 500 mg twice daily), and increased under specialist by 500mg as tolerated.
- The usual maintenance dose is 2 grams daily, but doses of up to 3 grams daily are sometimes used.
- As there are potential teratogenic effects, tablets and capsules should be swallowed whole and should NOT be opened or crushed to eliminate the risk of exposure such as inhalation.
- Direct contact with the skin or mucous membrane should be avoided.

Cautions

Vaccinations: live vaccines should be AVOIDED (i.e. oral polio, MMR, BCG, yellow fever and oral typhoid). Annual flu and pneumococcal vaccination is recommended.

Side effects

- **Gastrointestinal disturbances**: most common side effect (nausea, vomiting, abdominal pain, diarrhoea)
- **Infection**: Decreased resistance to infection- including opportunistic infection
- **Bone Marrow Suppression**: Patients should be advised to report immediately any signs or symptoms of bone marrow suppression e.g. infection or inexplicable bruising or bleeding
- **Cancer risk**: Patients receiving immunosuppressant regimens are at increased risk of lymphomas and skin malignancies. Avoiding excessive exposure to the sun and use of high factor sunscreens are advised.
- Progressive multifocal leukoencephalopathy (PML) should be considered in differential diagnosis in patients reporting neurological symptoms on treatment with mycophenolate.
- Metabolic (gout, hyperlipidemia, hypertension).

Contraindications

Hypersensitivity to Mycophenolate Mofetil

PREGNANCY/BREASTFEEDING: This drug is contra-indicated in pregnancy and breastfeeding as it has the potential to affect the development of the unborn child (exclude before starting and avoid for 6 weeks after discontinuation).

Advice to patients:
Women of childbearing potential receiving mycophenolate mofetil should be advised to use effective contraceptive prior to, during and for **six weeks** following the discontinuation of therapy.

Drug Interactions

- Antacids with magnesium and aluminium hydroxide reduce the absorption of Mycophenolate Mofetil and therefore not taken at the same time.
- Cholestyramine should not be taken at the same time of day as it will impair the absorption of Mycophenolate Mofetil.
- NSAIDS (and other nephrotoxic drugs) should be used with caution.
- Azathioprine administration concurrently with Mycophenolate should be avoided.
- Iron preparations may lead to a reduction in absorption of Mycophenolate.

Hospital Specialist Responsibilities

- Ensure the patient / carer is well informed about their therapy and accepts shared care.
- Ensure that the patient understands the treatment regime and any monitoring or follow up that is required (using advocacy if appropriate).
- Initiate treatment and prescribe until the patient is stable on treatment and the GP formally agrees to share care. – After 6 months of treatment success.
- Send a letter to the GP requesting shared care at month four if treatment has been deemed successful. The GP will start prescribing at month six.
- Clinical and laboratory supervision of the patient by blood monitoring and routine clinical follow up on a regular basis. Ensure results are relayed to the GP throughout treatment
- Send communications by way of
  a) letter detailing current drug, dose and frequency of monitoring

b) most recent relevant blood results
c) notification of DNAs to the GP after each clinic

- Evaluation of any reported adverse effects reported by GP or patient.
- Advise GP on review, duration or discontinuation of treatment where necessary.
- Ensure that back-up advice is available at all times.
- Monitor disease response to treatment and need to continue therapy

GP Responsibilities

- Send a letter to the specialist only if declining shared care.
- Check and re-enforce patients understanding of the nature, effect, potential side effects of the drug and any monitoring requirements before prescribing and contact the specialist for clarification where appropriate.
- Report any adverse events to the consultant and/or CSM, where appropriate.
- Help in monitoring the progression of the disease initially every 6 weeks then 3 monthly.
- Prescribe the drug treatment as described

Patients Responsibilities

- Ensure they have a clear understanding of their treatment.
- Report any adverse effects to their GP or specialist.
- Report any changes in disease symptoms to the GP or specialist.
- Alert GP and / specialist of any changes in circumstances which could affect management of disease e.g. plans for pregnancy

Events and Actions

Laboratory Events	Values	Action
Elevation in liver enzymes (AST, ALT)	>2 x Normal	Stop, repeat LFTs. Discuss with specialist.
MCV	>110 fl	No action if RBC folate, serum B12, TFT and LFTs are normal. Consider haematological opinion.
WBC	< 3.5 x 109/L	**STOP + Seek advice.**
Neutrophils	< 1.5 x 109/L	
Platelets	< 100 - 150 x 109/L	
Sequential fall in WBC or neutrophils	> 10% on 3 occasions	
Sequential fall in Platelets > 10	> 10% on 3 occasions	Stop – unless falls are from high level e.g. 600, 500, 400 x 109/L, which are a response to treatment.

CCG responsibilities

- To provide feedback to Trust via Trust Medicines Committee.
- Support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
- To support Trusts in resolving issues that may arise as a result of shared care

Long Term Follow Up:

Once patient's skin condition is stable and a dose regimen is established the patient can have 3 monthly appointments along with blood test monitoring. This should alternate with GP and hospital specialist.

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the BNF.

REMEMBER if unsure at any point: Contact the specialist for the condition.

Call Basildon Hospital switchboard 01268524900, and dial the extension

Consultant Name	Secretary's name	Extension
Dr M Khorshid	Linda Ann Woodhead	8043
Dr N Jasani	Linda Ann Woodhead	8043
Dr Mehta	Maureen Ates	8654
Dr G Skibinska	Anna Reynolds	3418
Dr R Suchak	Chris Burke	4576
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Call Southend hospital for

Consultant Name	Secretary's name	Direct Line
Dr P Gatt	Lisa Roberts	01702385332
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