

**Shared Care Guideline**

# Mycophenolate mofetil for pemphigus and other dermatological diseases (Adults)

It is vital for safe and appropriate patient care that there is a clear understanding of where clinical and prescribing responsibility rests between Consultants and General Practitioners (GPs).

This guideline reinforces the basic premise that:

When clinical and / or prescribing responsibility for a patient is transferred from hospital to GP, the GP should have full confidence to prescribe the necessary medicines. Therefore, it is essential that a transfer of care involving medicines that a GP would not normally be familiar with, should not take place without the “sharing of information with the individual GP and their mutual agreement to the transfer of care.”

These are not rigid guidelines. On occasions, Consultants and GPs may agree to work outside of this guidance. As always, the doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

**Indications:**

Unlicensed indications: severe eczema and pemphigus.

**Dosage and administration:**

Initial dose: 500mg orally twice daily

After 1 month if monitoring stable: 1g orally in the morning, 500mg in the evening

After further month if monitoring stable: 1g orally twice daily.  
Review after 3 months.

**Additional Information**

- Patients should be instructed to report immediately any evidence of infection, unexpected bruising, bleeding or any other manifestation of bone marrow depression
- Increase susceptibility to skin cancer – avoid exposure to strong sunlight
- Mycophenolate should not be given to women who are pregnant, or likely to become pregnant. Effective contraception must be used before starting therapy, during therapy, and for six weeks following discontinuation of therapy

**Monitoring requirements:**

Before treatment:

- Full blood count (FBC) including platelets, urea and electrolytes (U&Es), creatinine, liver function tests (LFTs), Chest X-ray

During treatment:

- FBC, LFTs, U/Es and creatinine weekly for the first month then monthly thereafter if stable
- Annual fasting lipids (HDL, Cholesterol, HDL/Cholesterol ratio)

**Secondary Care responsible for 3 months whilst patient stabilised, thereafter responsibility for monitoring rests with the GP**

**Action to be taken if abnormal results/adverse effects:**

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| <ul style="list-style-type: none"> <li>• WBC &lt; 3.5 x 10<sup>9</sup>/l</li> </ul>         | Check neutrophil count   |
| <ul style="list-style-type: none"> <li>• Neutrophils &lt; 2.0 x 10<sup>9</sup>/l</li> </ul> | Monitor weekly. If it falls below 1.5 x 10 <sup>9</sup> /l STOP DRUG and contact consultant. |
| <ul style="list-style-type: none"> <li>• Platelets &lt; 150 x 10<sup>9</sup>/l</li> </ul>   | Monitor weekly. If drop below 100 x 10 <sup>9</sup> /l contact helpline                      |
| <ul style="list-style-type: none"> <li>• Abnormal bruising</li> </ul>                       | Repeat FBC and act on results as above   |
| <ul style="list-style-type: none"> <li>• Sore throat</li> </ul>                             | Repeat FBC and act on results as above   |

**Please note that in addition to absolute values for haematological indices, a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance.**

**Contraindications:**

- Mycophenolate should not be given to women who are pregnant, or likely to become pregnant. Effective contraception must be used before beginning therapy, during therapy, and for six weeks following discontinuation of therapy
- Mycophenolate is contraindicated in women who are breastfeeding.
- Live vaccines are contra-indicated in patients receiving mycophenolate on theoretical grounds.
- Hypersensitivity to mycophenolate mofetil or mycophenolic acid.

**Drug interactions:**

- Rifampicin-reduces plasma concentration of active metabolite of mycophenolate
- Antacids and proton pump inhibitors – absorption of mycophenolate reduced
- Metronidazole possibly reduces bioavailability of mycophenolate
- Norfloxacin possibly reduces bioavailability of mycophenolate
- Cholestyramine should not be taken at the same time of day as it will impair the absorption of Mycophenolate
- Sevelamer — administer one hour apart from mycophenolate
- Oral Iron should not be taken at the same time of day as it will impair the absorption of Mycophenolate -
- Aciclovir – mycophenolate increases aciclovir plasma levels (significant only in renal impairment)

**Cautions:**

- Active serious digestive system disease (risk of haemorrhage, ulceration and perforation).
- Elderly (increased risk of infection, gastrointestinal haemorrhage and pulmonary oedema)

**Adverse Effects:**

Nausea, diarrhoea GI inflammation, ulceration and bleeding, cough, dyspnoea, hyperglycaemia, tremor, dizziness, headache, flu-like syndrome hepatitis, jaundice, pancreatitis, hypertension, hypotension, tachycardia, insomnia, blood disorders (including leucopenia, anaemia, thrombocytopenia, pancytopenia and red cell aplasia), disturbances of electrolytes and lipids, malignancy (particularly of the skin), renal impairment, progressive multifocal leukoencephalopathy, interstitial lung disease, pulmonary fibrosis, alopecia, rash.

**Specialist responsibilities:**

- Discuss with the patient the benefits and side effects of treatment with mycophenolate
- If the patient is a woman of child bearing potential or male – ensure that they are aware of the importance of effective contraception and the need to discuss with their consultant if they wish to become pregnant
- Ensure baseline monitoring of full blood count and biochemical profile.
- Discuss how the patient / carer can be aware of possible signs of mycophenolate toxicity or intolerance
- Ensure that the patient understands and accepts their responsibilities (see section below)
- Seek consent for treatment and document in the patient's notes.
- Prescribe first 3 months of mycophenolate, or until patient is stable
- Provide written instruction to the GP for initiation and escalation of mycophenolate.
- Review the patient at the intervals specified below to monitor the patient's disease activity, the efficacy of the treatment and the ability to tolerate it, and consider whether continuation of treatment is appropriate.
- Discontinue if no response or patient has a significant adverse effect.
- Promptly communicate with the GP via a clinic letter any changes in treatment, results of monitoring undertaken, and assessment of adverse events. The clinic letter should clearly state if the dose has remained the same or if a dose adjustment had been made – specifically highlighting the new dose in comparison with the preceding one.
- Advise GPs when to stop treatment.
- Provide clear arrangements for back-up, advice and support.
- Report serious adverse events to the Committee on Safety of Medicines (CSM).

**GP's responsibilities:**

- Provide the patient with monthly repeat prescriptions of medication following written instructions for initiation and escalation by the specialist. The patient should allow at least 48 hours for the prescription from the GP to be generated.
- Refer promptly to the specialist if there is a change in the patient's status or concerns regarding

- compliance. In most cases, do not stop treatment without discussion with the Dermatology Consultant
- If patient fails to attend more than 2 monitoring visits it is not safe to continue treatment – contact the Dermatology Consultant for advice.
  - Report serious adverse events to the specialist and CSM.
  - Administer Pneumococcal Vaccine/ Pneumovax® II and annual influenza vaccines.
  - Consider passive immunisation with Varicella zoster immunoglobulin in non-immune patients exposed to chicken pox or shingles.

- Patient responsibilities:**
- Read the written patient information provided about the drug and have a clear understanding of the risks / benefits of mycophenolate treatment.
  - Attend for blood tests.
  - Report any adverse effects to their GP and/or specialist whilst treated with mycophenolate.
  - Limit alcohol to national safe weekly limits
  - Take monitoring booklet every time the patient sees the GP, has a hospital appointment or visits the pharmacist.

**Secondary care review: During initiation:** 4 – 6 weekly until controlled  
**Once disease controlled:** Annual review by consultant

Availability: Prescribe product with lowest acquisition cost.

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