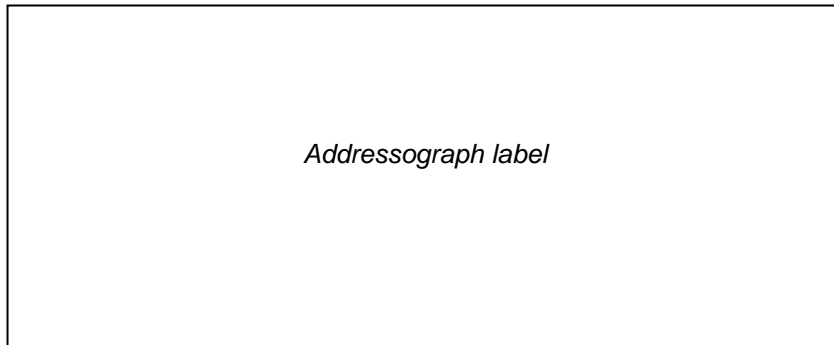


Further copies can be obtained from:

Pharmacy Department, Great Western Hospital  
NHS Wiltshire



**Patient's Name** \_\_\_\_\_

**Consultant Name** \_\_\_\_\_

**Consultant Signature** \_\_\_\_\_

**Date** \_\_\_\_\_

**I agree to your request to prescribe Mycophenolate in accordance with the attached shared care guideline:**

**GP Name** \_\_\_\_\_

**GP Signature** \_\_\_\_\_

**Date** \_\_\_\_\_

# Mycophenolate Mofetil Tablets (TLS Amber)

Please see page 2 for the full list of indications covered by this guideline

## AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines how responsibility for prescribing mycophenolate mofetil tablets might be shared between specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes this medication legally assumes clinical responsibility for mycophenolate mofetil capsules/tablets and the consequences of its use.

## RESPONSIBILITIES and ROLES

Specialist responsibilities	
1	Initiate treatment and prescribe first month of treatment.
2	Discuss the benefits and side effects of treatment with the patient (including the risk of bone marrow suppression and symptoms to be aware of) and emphasise the importance of regular monitoring.
3	Ensure compatibility of mycophenolate with other concomitant medication.
4	Ask the GP whether he or she is willing to participate in shared care, and discuss the shared care arrangement with the patient & obtain their consent.
5	Supply GP with summary within 14 days of a hospital out-patient review or in-patient stay.
6	Review the patient's condition and monitor response to treatment at least annually or as deemed clinically necessary.
7	Give advice to the GP on ongoing prescribing, monitoring and when to stop treatment.
8	Report adverse events to the MHRA & GP.
9	Ensure that clear backup arrangements exist for GPs to obtain additional advice and support should they need it.

General Practitioner responsibilities	
1	Reply to the request for shared care as soon as practicable.
2	Prescribe medicine at the dose recommended by the specialist.
3	Ensure compatibility of mycophenolate with other concomitant medication.
4	Undertake monitoring as per schedule on page 3 and refer to the specialist for advice on dosage adjustments.
5	Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
6	Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
7	Stop treatment on the advice of the specialist.
8	Report adverse events to the specialist and MHRA.

Patient's role	
1	Attend all appointments with GP and specialist, including appointments for blood tests and other monitoring.
2	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
3	Share any concerns in relation to treatment with medicine.
4	Inform specialist or GP of any other medication being taken, including over-the-counter products.
5	Report any adverse effects to the specialist or GP whilst taking the medicine.

## BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Email address:
Specialist (Rheumatology):			
Dr E Price – Consultant Rheumatologist	01793 604314	2112	<a href="mailto:Elizabeth.Price@gwh.nhs.uk">Elizabeth.Price@gwh.nhs.uk</a>
Dr L Williamson – Consultant Rheumatologist	01793 604318	1263	<a href="mailto:Lyn.Williamson@gwh.nhs.uk">Lyn.Williamson@gwh.nhs.uk</a>
Dr D Collins – Consultant Rheumatologist	01793 604317		<a href="mailto:David.Collins@gwh.nhs.uk">David.Collins@gwh.nhs.uk</a>
GWH Medicines Information	01793 605029		<a href="mailto:medinfo@gwh.nhs.uk">medinfo@gwh.nhs.uk</a>
Rheumatology Team – Osprey Department	01793 604323		

**SUPPORTING INFORMATION****Rationale for use/Indications:**

- Mycophenolate is an Inosine monophosphate dehydrogenase (IMPDH) inhibitor, which acts by selectively suppressing the immune system
- If used outside of the indication listed below the specialist should liaise with the GP and provide background literature before the appropriateness of a shared care agreement is assessed.

This guideline covers use in adults for the treatment of SLE, Sjogren's Syndrome, rheumatoid arthritis, polymyalgia, dermatomyositis, polymyositis, polyarteritis, auto-immune haemolytic anaemia and chronic refractory idiopathic thrombocytopenia purpura.

**Dosage and administration**

- The starting dose is 500mg OD increased according to response to a maximum dose of 3g daily in divided doses.
- Dose adjustment may be required in patients with severe renal impairment.
- Mycophenolate should be taken with or immediately after food.
- Therapeutic effect may only be evident after several weeks or months of treatment

**Contra-indications and precautions for use**

- Contraindicated in patients with hypersensitivity to mycophenolate, mycophenolic acid or any of the excipients.
- Contraindicated in women who are breastfeeding
- Effective contraception should be used prior to therapy, during therapy and for six weeks following discontinuation of therapy
- Patients should be advised to limit exposure to sunlight and ultra violet (UV) light by wearing protective clothing and high factor sunscreen
- Use with caution in patients with active serious digestive system disease.

See SPC for full list of contraindications and precautions for use.

**Side-effects**

Very Common ( $\geq 1/10$ )	Leucopenia, thrombocytopenia, sepsis, herpes simplex, anaemia, nausea/vomiting, GI candidiasis, herpes zoster, abdominal pain, diarrhoea, UTI
Common ( $\geq 1/100$ to $<1/10$ )	Loss of weight, loss of appetite

Refer patient back to the specialist if any of these side-effects cause concern. Refer to the SPC for a full list of adverse effects & further information <http://www.medicines.org.uk>.

*This medicine does not have black triangle (▼) status. Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the MHRA.*

**Monitoring**

Parameter	Frequency of monitoring	Action (adjustment and referral back to hospital)
Full Blood Count	Monthly for 6 months and then as indicated	If the patient becomes neutropenic $<1.3 \times 10^9/\text{microlitre}$ stop treatment and refer to specialist
Hepatic function (incl. dipstick urinalysis)	Baseline	
LFTs	Monthly for 6 months and then as indicated	Stop and refer to specialist if three times upper limit. If there is a persistent downward trend, don't stop but refer to specialist.
Unexplained bruising or bleeding	Continuous	Discontinue treatment and refer to specialist

### Drug Interactions

- Caution should be used with medicinal products that interfere with enterohepatic circulation because of their potential to decrease efficacy of mycophenolate
- Vaccinations may be less effective during treatment with mycophenolate and the use of live attenuated vaccines should be avoided
- Azathioprine – do not use in combination with mycophenolate
- Absorption of mycophenolate is reduced by antacids, PPIs and cholestyramine
- Monitor MPA exposure if mycophenolate is administered concomitantly with rifampicin and adjust dosage to maintain clinical efficacy
- Avoid concomitant use of clozapine due to increased risk of agranulocytosis

See SPC for full list of interactions.

### Cost

Mycophenolate Mofetil 500mg Tablets x 50 - £14.08

**Only prescribe tablets, capsules are not cost-effective.**

(NHS Prescription Service 15<sup>th</sup> June 2012)

### References

- Electronic Medicines Compendium. Summary of Product Characteristics. Mycophenolate Mofetil 250mg Capsules (Accord Healthcare Ltd)

<http://www.medicines.org.uk/EMC/medicine/25952/SPC/Mycophenolate+Mofetil+250+mg+Capsules/>

- BNF 63, March 2012

### Author

Katherine Roe, Formulary Pharmacy Technician, GWH

### Date written

November 2012

### Date of review

December 2015