

PRESCRIBING GUIDANCE
MYCOPHENOLATE MOFETIL for the treatment of lupus nephritis and systemic vasculitis

For the latest information on interactions and adverse effects, always consult the latest version of the Summary of Product Characteristics (SPC), which can be found at: <http://www.medicines.org.uk/>

Approval and Authorisation

Approved by	Job Title	NAME	Date
Renal CG	Chair	Dr B Alchi	18/07/2016
RBFT DTC	Chair	S Hussain	10/11/2017
GP MPC	Chair	Dr W Beacham	21/06/2017

Change History

Version	Date	Author	Reason

Introduction

This guidance has been prepared to support healthcare professionals in the implementation of shared care management of patients who have been prescribed mycophenolate mofetil for the treatment of lupus nephritis and systemic vasculitis.

Although unlicensed for this use, evidence from a Cochrane review of RCTs and quasi-RCTs suggests that MMF is as effective as cyclophosphamide at inducing remission in lupus nephritis but with a lower risk of ovarian failure. For maintenance therapy in lupus nephritis the Cochrane review found that MMF was more effective than azathioprine for preventing relapse with no increase in clinically important adverse events (see NICE ESUOM36 November 2014).

MMF is an alternative for patients who are intolerant of or in which the use of azathioprine and methotrexate for the maintenance of remission of systemic vasculitis (see BSR and BHPR guideline for the management of adults with ANCA-associated vasculitis; Ntatsaki et al; Rheum 2014).

Dose

The recommended dose is up to 3g daily, taken in 2 – 4 divided doses. Patients on 2g benefit the most without the risk of over immunosuppression. It may take 6 – 12 weeks before therapeutic benefit is seen.

If diarrhoea develops, consider switching to mycophenolic acid (Myfortic®). 500mg of MMF is equivalent to 360mg Myfortic®.

Consider checking MPA level in patients who do not respond. Aim for trough level above 3mg/L (target range 3.5 – 4.5mg/L).

Administration

MMF should be taken after meals to reduce nausea and diarrhoea.

Cautions

Patients should try to avoid contact with people who have active chickenpox or shingles and should report any such contact to their GP or hospital specialist.

Contraindications

- Hypersensitivity to MMF
- MMF 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 6 weeks following discontinuation of therapy.
- MMF is contra-indicated in women who are breastfeeding.

Side effects

- Gastro-intestinal disturbances - Nausea, vomiting, diarrhoea, constipation and abdominal discomfort
- Bone marrow suppression (leucopenia, thrombocytopenia, anaemia) and therefore increased risk of infection
- Increased risk of lymphoma and skin cancer

Interactions

- Antacids containing aluminium and magnesium reduce MMF absorption. Separate administration by 2 – 3 hours.
- Rifampicin – reduce plasma concentration of active metabolite of MMF.
- Aciclovir – causes increase in concentrations of both MMF and aciclovir in renal impairment
- Patients should avoid 'live' vaccines such as oral polio, oral typhoid, MMR, BCG, chicken pox/shingles and yellow fever, whilst on immunosuppressive therapy. Contact hospital specialist for advice on any vaccinations if required.

Criteria for Use

RESPONSIBILITIES and ROLES

Specialist responsibilities	
1	Initiate treatment and prescribe until the GP formally agrees to share care (a supply of two weeks or original pack as per agreement).
2	Carry out baseline and subsequent monitoring.
3	Send a letter to the GP requesting shared care for the patient.
4	Routine clinic follow-up on a regular basis.
5	Send a letter to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated.
6	Evaluation of any reported adverse effects by GP or patient.
7	Contact GP if results of blood monitoring are abnormal with advice for e.g. suspend treatment, decrease dose etc.
8	Advise GP on review, duration or discontinuation of treatment where necessary.
9	Inform GP of patients who do not attend clinic appointments.
10	Ensure that backup advice is available at all times
Monitoring requirements and actions (to be undertaken by the hospital)	
	<ul style="list-style-type: none"> • Pre-treatment FBC and renal profile. • Subsequent Monitoring <ul style="list-style-type: none"> ▪ FBC – weekly for 4 weeks after each dose increase, thereafter monthly.
General Practitioner responsibilities	
1	Monitor patient's overall health and well being.
2	Prescribe the drug treatment as described
3	Report any adverse events to the hospital specialist, where appropriate
4	Help in monitoring the progression of disease.
5	Alert the hospital of any suspected non-compliance with treatment.
Patient's / Carer's role	
1	Ask the specialist for information, if he or she does not have a clear understanding of the treatment.
2	Tell the specialist of any other medication being taken, including over-the-counter products.
3	Read the patient information leaflet included with your medication and report any side effects or concerns you have to the specialist or GP

BACK-UP ADVICE AND SUPPORT

Contact details	Specialist	Telephone No.	Email address:
Consultant nephrologists	Dr Bassam Alchi Dr Lindsey Barker Dr Nitin Bhandary Dr Cian Chan Dr Oliver Flossmann Dr Mobin Mohteshamzadeh Dr Emma Vaux	(0118) 322 1889	