

**Basingstoke,
Winchester &
Southampton
District
Prescribing
Committee**

Indications	Mycophenolate mofetil is licensed for the prevention of transplant rejection. It is used “off licence” in connective tissue diseases (including systemic lupus erythematosus, Sjogren’s syndrome, rheumatoid arthritis, mixed connective tissue disease, systemic sclerosis, vasculitis, myositis and overlap syndromes) which have not responded to standard first line treatments e.g. hydroxychloroquine, methotrexate and azathioprine.
Dose & response	<ul style="list-style-type: none"> • Usual maintenance dose is 1g bd. Occasionally higher doses are used up to a maximum of 3g daily. • Initiating treatment: 500mg od for the first week, 500mg bd for the second week, 1g morning and 500mg evening for the third week, then 1g bd. • Consider lower doses if renal or hepatic impairment or older person. • Duration of therapy is indefinite. May be stopped on specialist advice after prolonged period of disease remission. • Response to treatment is usually seen within 3 months.
Specialist responsibilities	<ul style="list-style-type: none"> • Prescribe the first 2-3 months treatment • Request blood tests and monitor results until dose stable – usually 2-3 months • If dose is increased, request additional blood tests and monitor results until back to previous schedule (see below for monitoring schedule) • Counsel patients about side effects
GP Responsibilities	<ul style="list-style-type: none"> • Take over prescribing once dose is stable and asked to do so by the specialist (usually 2-3 months) • Arrange ongoing monitoring at the recommended frequencies and review results before prescribing. • Report any adverse events to the specialist and stop treatment on their advice or immediately if an urgent need arises (see monitoring section). • Report any worsening of control of the condition to the specialist. • Annual influenza vaccinations are recommended for patients with inflammatory arthritis. • Annual influenza vaccinations are recommended for patients with inflammatory arthritis. <p>Recommended monitoring for new DMARDs</p> <ul style="list-style-type: none"> • FBC, Cr (or GFR), ALT, albumin every 2 weeks until stable dose for 6 weeks • Then monthly FBC, Cr or GFR, ALT, albumin for 3 months • Then FBC, Cr or GFR, ALT, albumin at least every 12 weeks • For dose increases -FBC, Cr or GFR, ALT, albumin every 2 weeks until stable dose for 6 weeks then back to previous schedule
Acts to be taken in response to monitoring	<p>Thresholds at which to discontinue treatment and contact Rheumatology treatment for urgent review:</p> <ul style="list-style-type: none"> • WCC<3.5 x10⁹/L • Neutrophils<1.6 x10⁹/L • Unexplained eosinophilia>0.5 x10⁹/L • Platelets<140 x10⁹/L • MCV>105 • ALT>100 units/L • Unexplained fall in albumin • Creatinine>30% above baseline +/- GFR<60

Contra-indications	<ul style="list-style-type: none"> • Pregnancy & breast feeding – patients (both sexes) of reproductive age should be advised to use contraception during treatment and for at least 3 months after stopping. • Active infection and immunodeficiency syndromes • Bone marrow failure indicated by cytopenia, anaemia • Immunisations- Avoid live immunisations. Pneumococcal & flu vaccines can be given but pneumococcal revaccination is not recommended. Passive immunisation may be given with varicella zoster immunoglobulin in non-immune patients exposed to chicken pox or shingles. Contact specialist for advice.
Cautions	<ul style="list-style-type: none"> • Elderly patients may be at increased risk of infections, gastrointestinal haemorrhage and pulmonary oedema • Active serious gastrointestinal disease – increased risk of haemorrhage, ulceration and perforation • Elective surgery- suspend treatment (increased risk of infection) • Chronic kidney disease (stable)- doses greater than 1g bd should be avoided in patients with severe chronic kidney disease.
Important adverse effects & management	<ul style="list-style-type: none"> • Diarrhoea, nausea, vomiting, abdominal pain - Withhold treatment if does not resolve or is severe and discuss with specialist. • Severe sore throat, abnormal bruising- Request urgent FBC and withhold treatment until results are known • Haematopoietic suppression- may occur abruptly. Any profound drop in white cell or platelet count calls for immediate withdrawal of treatment and urgent referral for supportive treatment. • Patient develops significant infection or is systemically unwell- Withhold treatment and discuss with specialist. • Increased risk of skin malignancies – patients should be educated about sun protection and skin surveillance.
Important Drug Interactions	<ul style="list-style-type: none"> • Absorption of mycophenolate is reduced by oral iron, antacids, cholestyramine and PPIs • Azathioprine administration concurrently with mycophenolate should be avoided • Bioavailability of mycophenolate increased by rifampicin

Reference: <https://www.medicines.org.uk/emc/medicine/24288>. Mycophenolate mofetil SPC. Accessed 29th Apr 2015

Contact numbers for urgent GP advice

Southampton - Nurse specialist advice line 023 8120 5352 or bleep SpR 1801 (Mon-Fri 9-5). Out of hours – on-call consultant via hospital switchboard

Basingstoke - Administration team 01256 312768, fax 01256 313653, advice line (answerphone) 01256 313117 or on-call consultant via switchboard

Winchester – Administration team 01964 824150, Advice line 01962 824256, on-call SpR bleep 3425 via switchboard