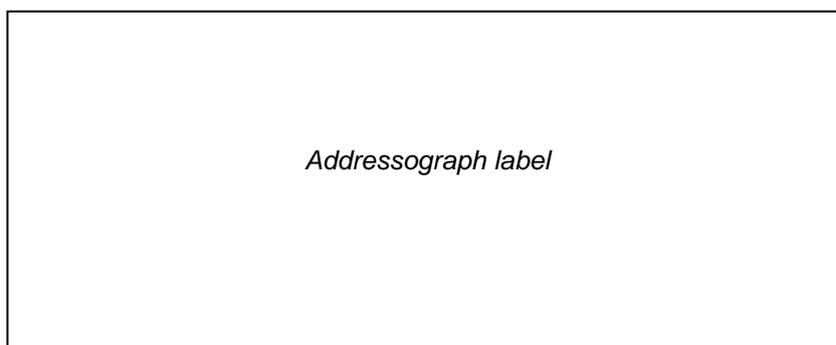


Ciclosporin must be prescribed by brand as specified by the specialist.

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 Ciclosporin in accordance with the attached shared care guideline:

GP Name _____

GP Signature _____

Date _____

Oral Ciclosporin (TLS Amber)

Shared Care Guideline: For the treatment of Severe Rheumatoid Arthritis in those who have failed to respond to disease modifying drugs.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines how responsibility for prescribing oral ciclosporin 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 oral ciclosporin and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities	
1	Initiate treatment and prescribe at least the first month supply of medication.
2	Discuss the benefits and side effects of treatment with the patient and emphasise the importance of regular monitoring.
3	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.
4	Ensure compatibility of ciclosporin with other concomitant medication.
5	Supply GP with summary within 14 days of a hospital out-patient review or in-patient stay, specifying brand to be prescribed.
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 concerning ongoing prescribing, monitoring, dosage adjustments 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 in the brand and at the dose recommended by the specialist.
3	Undertake monitoring as per monitoring schedule on page 3.
4	Ensure compatibility of ciclosporin with other concomitant medication.
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	Elizabeth.Price@gwh.nhs.uk
Dr L Williamson – Consultant Rheumatologist	01793 604318	1263	Lyn.Williamson@gwh.nhs.uk
Dr D Collins – Consultant Rheumatologist	01793 604317		David.Collins@gwh.nhs.uk
GWH Medicines Information	01793 605029		medinfo@gwh.nhs.uk
Rheumatology Team – Osprey Department	01793 604323		

SUPPORTING INFORMATION

Indications

This guideline covers treatment for:

- Severe Rheumatoid Arthritis in those who have failed to respond to disease modifying drugs
- If used outside of this indication the specialist should liaise with the GP and provide background information, before the appropriateness of a shared care agreement is assessed.

Dosage and administration

- Titrate according to tolerability. DO NOT EXCEED 4mg/kg/day
- The total daily dose is given in two doses, twelve hours apart
- Injectable ciclosporin should be administered in **hospital only**
- If no adequate response after 3 months of treatment at the maximum permitted or tolerated dose, treatment should be discontinued
- Patients should be re-evaluated after 6 months of treatment and therapy should only be continued if benefits of treatment outweigh the risks

Contra-indications and precautions for use (see also drug interactions)

- Hypersensitivity to ciclosporin or any of the excipients
- Contraindicated in abnormal renal function, uncontrolled hypertension, uncontrolled infections and malignancy.
- Avoid excessive exposure to UV light, including sunlight
- Contraindicated in patients under 18 years of age

See SPC for full list of contra-indications and precautions.

Side-effects

Most commonly experienced side effects (mainly in the initial period of administration) include:

- Impaired renal function (dose dependant & reversible)
- Hypertension & convulsions (with high doses &/or high trough levels)
- GI disturbance (abdominal pain, anorexia, nausea, vomiting, diarrhoea), which may affect absorption
- Hyperkalaemia
- Gingival hypertrophy (oral hygiene important)
- Subjective burning in hands & feet
- Hypertrichosis.
- Increased risk of infection
- Tremor & fatigue

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)
Blood pressure	Monthly	If hypertension develops which cannot be controlled by appropriate anti-hypertensive therapy the patient should be referred back to secondary care for review
Urea, creatinine & electrolytes	Measure serum creatinine at least twice before initiating treatment and monitor every 2 weeks for the first 3 months, and every 4 weeks thereafter.	If the serum creatinine increases by more than 30% above baseline the patient should be referred back to secondary care for review
LFTs	Monthly, then every 3 months	Refer if new change outside normal range or persistent downward trend
Lipid Profile	At baseline and 1 month after start of treatment	If increased lipids, restrict dietary fat and if appropriate consider dose reduction.

Drug Interactions – refer to BNF and SPC for full list

- Concomitant use of tacrolimus is contraindicated
- Concomitant use of rosuvastatin is contraindicated
- Vaccinations may be less effective, use of live attenuated vaccines should be avoided
- Caution if co-prescribed with lercanidipine, other nephrotoxic drugs, ACE inhibitors, ARIIA or potassium sparing diuretics
- Drugs that REDUCE ciclosporin levels include: Rifampicin, Carbamazepine, Phenobarbitone, Primidone, Phenytoin, Octreotide
- Drugs that INCREASE ciclosporin levels include: Erythromycin & other macrolides, Ketoconazole, Fluconazole, Itraconazole, Doxycycline, Diltiazem, Nircardipine, Verapamil, Methylprednisolone, Progestogens, Propafenone, Chloroquine, Metoclopramide, Amiodarone and grapefruit juice

Cost

100mg/1ml oral solution x 50ml - £103.55

10mg capsules x 30 - £8.22

25mg capsules x 30 - £18.95

50mg capsules x 30 - £36.41

100mg capsules x 30 - £69.11

(NHS Prescription Services 28th September 2012)

References:

- BNF 63, March 2012
- Electronic Medicines Compendium. Summary of Product Characteristics. Neoral Soft Gelatin Capsules, Neoral Oral Solution (Ciclosporin)

<http://www.medicines.org.uk/EMC/medicine/1307/SPC/Neoral+Soft+Gelatin+Capsules%2c+Neoral+Oral+Solution/>

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