## Ciclosporin (oral) for patients within adult services (non-transplant indications)

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| Version: | HNY v1.0 | Replaces version: | RDTC v1.1 |
| Clinical content last reviewed: | October 2023 | Next review date: | October 2025 |

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| **Version** | **Date published** | **Changes since previous version** |
| RDTC v1.0 | 14th February 2024 | Links and references updated to current versions. Severe hepatic impairment added as a condition requiring dose adjustment. Viral screening at baseline updated to recommend following local policies, reflecting other DMARD SCPs. Shingles vaccine information updated to reflect amended 2023 national schedule. Use in pregnancy updated to reflect amended 2023 BSR guidelines. |
| RDTC v1.1 | 26th November 2024 | Advice on shingles vaccine clarified to reflect potential eligibility of patients aged 50 years or older taking immunosuppressive therapy |
| HNY v1.0 | tbc | * HNY logos added
* Section 4: Transfer of monitoring and prescribing updated as per NHSE document - <https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf> and following wording added: To transfer from the specialist to primary care, the patient must be a) stable, i.e. the condition/indication is 'managed' appropriately, monitoring is within normal parameters, and b) the patient remains on the same dose that the specialist recommended.
* Section 5: Blood pressure (BP) added "required at least twice before starting treatment"
* Section 5: added Urinalysis
* Section 5: Wording re screening for viral infections changed from "as per local policy" to "at discretion of the treating clinician"
* Section 5: Added Cervical screening – check up to date
* Section 5: Initial monitoring – added Serum creatinine (for creatinine clearance) or calculated GFR should be repeated every 2 weeks for first 3 months, then monthly for 3 months
* Section 5: added for 3 months to "To be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly **for 3 months.**"
* Section 5: deleted "but may be sooner in some indications"
* Section 5: Added "brand of ciclosporin prescribed" to following: At initiation of shared care, communication to primary care should include **brand of ciclosporin prescribed**, current and ongoing dose, any relevant test results, date the next monitoring is required, anticipated duration of treatment, and stop date for ciclosporin (if applicable)
* Section 6: Removed monitoring of CRP & / or ESR
* Section 6: Frequency changed from monthly to "at least every 3 months"
* Section 10: Changed eosinophilia to unexplained eosinophilia
* Section 10: Mean cell volume greater than 105fl – changed wording in management section from "Consider interruption in treatment if there is a significant increase from baseline" to " Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are abnormal treat, if normal discuss with specialist team"
* Section 10: Added urinary protein and management
* Section 11: Hyperlink to UKHSA guidance updated to most recent version
* Section 13: Contact information updated to "Detailsfor contacting specialist must be included on clinic letter"
* Section 16: Hyperlink to Shared Care for Medicines Guidance updated
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**Local review and adoption**

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| **Local approval** | **Date** |
| Local content added |  |
| Approved for use by Humber and North Yorkshire ICB  |  |
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Clinical content has been reviewed and updated by the RDTC on the date indicated above. Every effort is made to keep the content up to date. These templates are provided to the North West and North East and Yorkshire ICBs for localisation and approval through standard ICB processes. The most recent version is available on the RDTC website at <https://rdtc.nhs.uk/prescribing-support-document/shared-care-protocol-ciclosporin-oral-for-adults-non-transplant/>.

This document is intended for use by NHS healthcare professionals and cannot be used for commercial or marketing purposes.

**Shared Care Protocol**

## Ciclosporin (oral) for patients within adult services (non-transplant indications)

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| Background | Ciclosporin is a potent immunosuppressant which is thought to act specifically and reversibly on lymphocytes. It is licensed for the prevention of transplant rejection, as well as some chronic inflammatory disorders. It is not licensed for all the conditions it is used to treat, however its use for the indications below is well established and supported by clinical specialists.This shared care protocol does not cover use post-transplant, or the treatment of people less than 18 years old. |
| Licensed and agreed off-label indications | Licensed indications: * Endogenous uveitis
* Nephrotic syndrome
* Rheumatoid arthritis
* Psoriasis
* Atopic dermatitis

This shared care protocol also includes treatment of chronic inflammatory conditions where off-label use of ciclosporin is appropriate, including, but not limited to, the following specialities and conditions:* Rheumatology (e.g. psoriatic arthritis, systemic lupus erythematosus, connective tissue disease, vasculitis)
* Dermatology (e.g. urticaria, inflammatory dermatoses, bullous conditions)
* Gastroenterology (e.g. severe ulcerative colitis)
* Renal medicine (e.g. vasculitis, lupus nephritis)
* Neurology (e.g. myasthenia gravis)

These indications are off-label. The specialist must specify the indication for each patient when initiating shared care and clearly state when use is off-label.This shared care protocol applies to adults aged 18 and over. |
| Locally agreed indications | *To be completed locally* |
| Initiation and ongoing dose regime | Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient’s dose has been optimised and with satisfactory investigation results for at least 12 weeks. To transfer from the specialist to primary care, the patient must be a) stable, i.e. the condition / indication is 'managed' appropriately, monitoring is within normal parameters, and b) the patient remains on the same dose that the specialist recommended. The duration of treatment and frequency of review will be determined by the specialist, based on clinical response and tolerability.All dose or formulation adjustments will be the responsibility of the specialist unless directions have been discussed and agreed with the primary care clinician.Termination of treatment will be the responsibility of the specialist.Initial stabilisation:Starting doses range from 2.5 mg/kg/day to 5 mg/kg/day in two divided doses depending on the indication. The selected dose will be tailored to the individual patient and decided by the specialist. In certain conditions higher doses may be used for a limited period, this should be under the direct supervision of the specialist.**The dose titration period must be prescribed by the initiating specialist.**Maintenance dose (following initial stabilisation):The maintenance dose will be tailored to the individual patient, and should be the lowest effective and well tolerated dose. The usual maximum dose is 5 mg/kg/day in two divided doses. Please note that, for rheumatology conditions, a patient may be initiated on more than one DMARD.**The initial maintenance dose must be prescribed by the initiating specialist.**Conditions requiring dose adjustment:* In patients with nephrotic syndrome and impaired renal function the initial dose should not exceed 2.5 mg/kg/day.
* Deteriorating renal function. See [section 10](#ten_ADRs).
* Severe hepatic impairment.

Elderly patients: dose selection should be cautious, and start at the low end of the dose range. |
| Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist | Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in the immediate future will prescribing and monitoring be transferred to primary care.Baseline investigations:* Height and weight
* Blood pressure (BP) – required at least twice before starting treatment
* HbA1c
* Full blood count (FBC)
* Urea and electrolytes (U&Es) & creatinine clearance (CrCl), ideally on two occasions prior to starting ciclosporin
* Serum magnesium
* Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST), albumin, and bilirubin
* Serum lipids and uric acid
* Urinalysis
* Screening for viral infections at discretion of the treating clinician, e.g. HIV, hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus
* Screening for lung disease, including tuberculosis, should be undertaken at clinician discretion on a case-by-case basis
* Cervical screening – check up to date
* Consider baseline pregnancy testing, if clinically appropriate
* Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, shingles, influenza, COVID-19)

Initial monitoring and at dose change: Serum creatinine (for creatinine clearance) or calculated GFR should be repeated every 2 weeks for first 3 months, then monthly for 3 monthsTo be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly for 3 months. After which, the transfer of prescribing to primary care should normally only take place when the patient has received a stable dose for at least 6 weeks and their blood and physical tests results have been satisfactory. It is anticipated that this should be around 12 weeks after initiation of the medicine. , * BP
* HbA1c
* FBC
* U&Es, including creatinine and CrCl
* Serum magnesium
* AST and/or ALT, albumin, and bilirubin
* Rheumatology patients: C-reactive protein (CRP) &/or erythrocyte sedimentation rate (ESR)

Following a dose change, repeat every 2 weeks until the dose has been stable for 6 weeks, then revert to previous schedule.After one month of treatment:* Serum lipids

More frequent monitoring is appropriate in patients at higher risk of toxicity. Monitoring of ciclosporin drug levels, where clinically appropriate, would usually be undertaken by the specialist if indicated.**Prescribing and dispensing of ciclosporin should be by brand name to avoid inadvertent switching**.If it is necessary to switch a patient to a different brand, this should be done cautiously under specialist supervision. The patient should be monitored closely for changes in the following:* Serum creatinine
* BP

At initiation of shared care, communication to primary care should include brand of ciclosporin prescribed, current and ongoing dose, any relevant test results, date the next monitoring is required, anticipated duration of treatment, and stop date for ciclosporin (if applicable).The specialist will retain the responsibility for monitoring the patient’s ongoing response to treatment, and advise if a dose change or treatment cessation is appropriate. This should usually be undertaken annually.When a patient is reviewed, advise primary care whether treatment should be continued and for how long, confirm the ongoing dose, and whether the ongoing monitoring outlined in [section 6](#six_monitoring) remains appropriate. |

## Ongoing monitoring requirements to be undertaken by primary care

If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

| **Monitoring** | **Frequency** |
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| * BP
* HbA1c
* FBC
* U&Es including creatinine and CrCl
* ALT and/or AST, albumin, and bilirubin
* ~~Rheumatology patients: CRP &/or ESR~~
 | At least every 3 months. Patients who have been stable for 12 months can be considered for reduced frequency monitoring on a case-by-case basis. **The exact frequency of monitoring to be communicated by the specialist team in all cases**. |
| * Serum lipids
* Uric acid
* Serum magnesium
 | 6 monthly |
| * Patients aged 60-79 years old are eligible for the shingles vaccine (herpes zoster). Patients aged 50 years or older and taking immunosuppressive therapy may also be eligible. Specialist input may be required. Refer to [Green Book Chapter 6 (Contraindications and special considerations)](https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6) and [Green Book Chapter 28a (Shingles)](https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a) for further details.
* **Annual** influenza ([The Green Book, Chapter 19](https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19)) vaccinations are recommended.
* COVID-19 vaccination is safe and recommended. See [Green Book Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a).
* Repeat pneumococcal vaccine may be indicated. See [Green Book Chapter 25](https://www.gov.uk/government/publications/pneumococcal-the-green-book-chapter-25).
 | * Shingles vaccination: single course (two doses).
* Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list.
* Other vaccinations as per national schedule.
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## Pharmaceutical aspects

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| Route of administration: | Oral |
| Formulation: | **Soft capsules**Capimune®: 25 mg, 50 mg, 100 mgCapsorin®: 25 mg, 50 mg, 100 mgDeximune®: 25 mg, 50 mg, 100 mgNeoral®: 10 mg, 25 mg, 50 mg, 100 mgSandimmun®: 25 mg, 50 mg, 100 mgVanquoral®: 10 mg, 25 mg, 50 mg, 100 mgGenerics: 25 mg, 50 mg, 100 mg**Oral solution**Neoral®: 100 mg/mLCapsorin®: 100 mg/mLSandimmun®: 100 mg/mL**Ciclosporin should be prescribed by brand and formulation, regardless of the indication**.Switching between formulations without close monitoring may lead to clinically important changes in blood-ciclosporin concentration.The switch from one oral ciclosporin formulation to another should be made under specialist supervision (see [section 5](#five_initial_monitoring)). Where possible, the brand preferred by the patient’s local health system should be chosen. |
| Administration details: | Ciclosporin should be taken in two divided doses equally distributed throughout the day, and on a consistent schedule with regard to time of day and in relation to meals.Neoral oral solution should be diluted prior to administration, preferably with orange or apple juice although other drinks can be used according to individual taste (licensed use). Grapefruit juice must not be used. The syringe should not come in contact with the diluent. If the syringe is to be cleaned, do not rinse it but wipe the outside with a dry tissue. The entire mixture should be stirred and taken immediately after preparation.  |
| Other important information:  | All oral dosage forms of ciclosporin, including capsules, contain a form of ethanol; a 500mg dose is the equivalent of up to approximately 15 ml beer or 6 ml wine. Neoral capsules and oral solution contain polyoxyl 40 hydrogenated castor oil, which may cause stomach upsets and diarrhoea.Neoral oral solution has a shelf life of 2 months once opened. |

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| Cautions and contraindications | This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see [BNF](https://bnf.nice.org.uk/drugs/ciclosporin/) & [SPC](https://www.medicines.org.uk/emc/search?q=%22ciclosporin%22) for comprehensive information.**Contraindications:** * Hypersensitivity to ciclosporin or any excipients
* Malignancy
* Uncontrolled hypertension
* Uncontrolled infection
* Concomitant use with Hypericum perforatum (St John’s Wort), tacrolimus, or substrates for P-glycoprotein or organic anion transporter proteins (OATP) e.g. bosentan, dabigatran, aliskiren (see [section 9](#nine_interactions))

**Cautions:**Note: cautions may vary with indication. See [SPC](https://www.medicines.org.uk/emc/search?q=%22ciclosporin%22) for more details. * Hepatic impairment
* Elderly; monitor renal function particularly closely
* Renal impairment – see [section 10](#ten_ADRs)
* Hypertension
* Hyperlipidaemia; ciclosporin may induce a small reversible increase in blood lipids.
* Hyperkalaemia; the risk of hyperkalaemia is increased by ciclosporin treatment.
* Hypomagnesaemia; ciclosporin increases magnesium excretion and can lead to symptomatic hypomagnesaemia, therefore supplementation may be required.
* Hyperuricaemia
* Vaccination may be less effective during treatment with ciclosporin. Live attenuated vaccines should be avoided (see [section 9](#nine_interactions)).
* Active herpes simplex infection; allow infection to clear before starting and withdraw if severe infections occur during treatment.
* Staphylococcus aureus skin infections; not an absolute contraindication if infection is controlled, but avoid erythromycin unless no other alternative (see [section 9](#nine_interactions)).
* Treat patients with malignant or pre-malignant conditions of skin only after appropriate treatment (and if no other option).
* Neurological Behçet's syndrome – monitor neurological status.
* Lymphoproliferative disorders; discontinue treatment.
* Pregnancy and breastfeeding, see [section 12](#twelve_pregnancy).
* All oral dosage forms of ciclosporin contain a form of ethanol, see [section 7](#seven_pharmaceutical).
* Due to the increased risk of skin cancer, exposure to sunlight and UV light should be limited by wearing protective clothing and using a sunscreen with a high protection factor. Avoid UVB irradiation or PUVA photochemotherapy.
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| Significant drug interactions | The following list is not exhaustive. Please see [BNF](https://bnf.nice.org.uk/drugs/ciclosporin/) & [SPC](https://www.medicines.org.uk/emc/search?q=%22ciclosporin%22) for comprehensive information and recommended management.**Ciclosporin is associated with a large number of interactions, some of which are significant enough to contraindicate concurrent use, require dose adjustment and/or additional monitoring (see** [**section 8**](#eight_cautions_cx)**).*** ***Hypericum perforatum* (St John’s Wort)**: contraindicated due to risk of decreased ciclosporin levels.
* **Substrates for P-glycoprotein or organic anion transporter proteins (OATP)** for which elevated plasma concentrations are associated with serious or life-threatening events e.g. bosentan, dabigatran, aliskiren. Concomitant use is contraindicated.
* **Digoxin, edoxaban**: monitoring recommended for digoxin. Dose adjustment recommended; levels increased by ciclosporin.
* **Statins, etoposide, repaglinide, ambrisentan**: plasma levels may be increased by ciclosporin; close clinical observation for toxicity is recommended. Doses of statins should be reduced, and temporarily withheld or discontinued if patients develop signs and symptoms of myopathy or have risk factors for severe renal injury secondary to rhabdomyolysis. Avoid simvastatin and rosuvastatin.
* **Colchicine**: levels of ciclosporin and colchicine may be increased. Close clinical observation for toxicity is recommended.
* **Inhibitors of CYP3A4, P-glycoprotein, or OATP**: may increase plasma levels of ciclosporin. Frequent assessment of renal function and careful monitoring for ciclosporin-related side effects may be required; seek specialist advice, e.g. nicardipine, metoclopramide, oral contraceptives, methylprednisolone (high dose), allopurinol, cholic acid and derivatives, protease inhibitors, imatinib, nefazodone.
* **Inducers of CYP3A4, P-glycoprotein, or OATP**: may reduce plasma levels of ciclosporin, e.g. barbiturates, carbamazepine, oxcarbazepine, phenytoin and fosphenytoin, primidone; nafcillin, intravenous sulfadimidine, probucol, orlistat, ticlopidine, sulfinpyrazone, terbinafine, apalutamide, enzalutamide, lumacaftor, pitolisant.
* **Macrolide antibiotics**: erythromycin can increase ciclosporin exposure 4- to 7-fold and may result in nephrotoxicity; avoid where possible. Clarithromycin and azithromycin also increase ciclosporin levels.
* **Nephrotoxic drugs**, e.g. aminoglycosides (including gentamicin, tobramycin), colistimethate, amphotericin B, ciprofloxacin, vancomycin, trimethoprim (+ sulfamethoxazole); fibric acid derivatives (e.g. bezafibrate, fenofibrate); non-steroidal anti-inflammatory drugs (NSAIDs, including diclofenac, naproxen, sulindac); melphalan, histamine H2-receptor antagonists (e.g. cimetidine, ranitidine); methotrexate: may have synergistic effects; close monitoring of renal function is recommended.
* **Doxycycline, tigecycline**: may increase ciclosporin concentrations. Monitoring is recommended.
* **Ticagrelor**: exposure increased by ciclosporin. Use with caution or avoid.
* **Potassium-sparing medicines**, including potassium-sparing diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists (ARBs), and potassium-containing medicines: may lead to significant increases in serum potassium. Control potassium levels as indicated.
* **Lercanidipine**: exposure increased by ciclosporin, avoid or use with caution and separate doses by at least 3 hours.
* **Nifedipine**: increased risk of gingival hyperplasia.
* **Azole antimycotics** (e.g. ketoconazole, fluconazole, itraconazole and voriconazole), verapamil, telaprevir: increase exposure to ciclosporin by at least 2-fold.
* **Caspofungin**: exposure increased by ciclosporin. Liver monitoring recommended.
* **Amiodarone and dronedarone**: increase ciclosporin levels. This interaction can occur for a long time after withdrawal of amiodarone, due to its very long half-life (about 50 days). Amiodarone increases serum creatinine concurrently.
* **Danazol, diltiazem** (at doses of 90 mg/day): may increase ciclosporin concentrations by up to 50%.
* **Rifampicin**: induces ciclosporin metabolism; ciclosporin doses may need to be increased 3- to 5-fold.
* **Rifaximin**: levels markedly increased by ciclosporin. Caution advised.
* **Octreotide, pasireotide, lanreotide**: decreases oral absorption of ciclosporin; increase in the ciclosporin dose or a switch to intravenous administration could be necessary.
* **Tacrolimus**: risk of pharmacokinetic interaction and nephrotoxicity. Avoid.
* **Everolimus and sirolimus**: ciclosporin increases levels of both drugs, concurrent use may increase serum creatinine.
* **Baricitinib, filgotinib, tofacitinib**: Increased risk of immunosuppression.
* **Ritonavir**: increases ciclosporin concentrations. Monitoring and ciclosporin dose adjustment may be needed.
* **Grapefruit and grapefruit juice**: increase ciclosporin exposure.
* **Vaccination**: During treatment with ciclosporin, vaccination may be less effective and the use of live attenuated vaccines should be avoided.
* **Aprepitant, netupitant**: predicted to increase ciclosporin levels. Use caution.
* **Anti-cancer medicines**: levels of either medicine may be altered, or risk of immunosuppression increased.
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## Adverse effects and management

As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance**.** For information on incidence of ADRs see relevant SPCs.

**Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit** [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

Advice based on shared care guidelines published by NHS England, and checked against current guidance.

| **Adverse effect** | **Management** |
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| Full blood count: * White blood cells less than 3.5x109/L
* Lymphocytes less than 0.5x109/L
* Neutrophils less than 1.6x109/L
* Platelets less than 140x109/L
* Unexplained Eosinophilia greater than 0.5x109/L
 | Withhold and discuss with specialist team. |
| Mean cell volume greater than 105 fL | Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If results of these additional investigations are abnormal, treat, if normal discuss with specialist team. |
| Infection requiring antibiotics | During serious infections temporarily withhold ciclosporin until the patient has recovered. Consider additional investigations (e.g. FBC), if clinically appropriate. |
| **Liver function tests**:ALT or AST greater than 100 units/L, or any sudden increases (e.g. double of baseline), Unexplained fall in serum albumin less than 30g/LJaundice | Withhold and discuss with specialist team.Assess for other causes of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication. |
| **Renal function**: Creatinine increase of greater than 30% from baseline over 12 months or CrCl reduces to less than 60mL/min | Withhold and discuss with specialist team.  |
| Hyperkalaemia | Review other medicines affecting potassium levels, e.g. ACE inhibitors, diuretics. Discuss with specialist team. |
| Elevated uric acid | If intending to treat as gout, discuss with specialist team due to the potential for interaction of urate-lowering medicines with ciclosporin. |
| Blood pressure | Manage hypertension according to local pathways. Care should be taken to avoid drugs which may interact (see [section 9](#nine_interactions)). Discuss the management with specialist team if required.Discuss with specialist if hypertension does not respond to treatment; discontinuation of ciclosporin may be indicated. |
| Urinary protein 2+ or more | Take a mid-stream sample, and:* if there is evidence of infection, this should be treated appropriately
* if the urine sample is sterile (no infection present) and the urinary protein 2+ or more persists on two consecutive measurements, stop ciclosporin and discuss with specialist team.
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| Hyperlipidaemia | Discuss with specialist team; reduction of ciclosporin dose may be considered. |
| Gum hypertrophy | Discuss with specialist team. |
| Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, purpura, mouth ulcers. | Check FBC immediately, withhold treatment while awaiting results, and discuss with the specialist team. See haematological monitoring above. |

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| Advice to patients and carersThe specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual drugs. | The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay: * Symptoms of chickenpox, or contact with a person with chickenpox or shingles.
* Sore throat, high temperature, skin rash, swollen glands, or any other signs or symptoms of infection.
* Signs or symptoms of liver problems, such as yellow skin or eyes (jaundice), itching all over, nausea or vomiting, diarrhoea, appetite loss.
* Unexplained bleeding or bruising, black stools, or blood in the vomit or stools.
* Seizures, confusion, disorientation, visual disturbance
* Gum swelling or growth (gingival hyperplasia)
* Suspected or confirmed pregnancy.

The patient should be advised:* To use effective contraception, and to take a pregnancy test if they think they could be pregnant. Patients should inform the specialist or GP immediately if they become pregnant or if they or their partners are planning a pregnancy.
* Tell anyone who prescribes them a medicine that they are taking ciclosporin. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.
* That vaccination in line with current national advice (e.g. for COVID-19, influenza) is safe and recommended.
* To avoid contact with people with chicken pox or shingles and report any such contact urgently to their primary care prescriber. If the patient is exposed, contact the specialist for advice. For detailed advice on risk assessment and post exposure prophylaxis following exposure to chicken pox and shingles, see:
	+ the [Green Book (Chapter 34, Varicella)](https://www.gov.uk/government/publications/varicella-the-green-book-chapter-34)
	+ UKHSA Guidance: [Guidelines on post exposure prophylaxis (PEP) for varicella and shingles](https://www.gov.uk/government/publications/post-exposure-prophylaxis-for-chickenpox-and-shingles)
* Patients have a small increased risk of skin cancers so should be advised to wear high factor sunscreen and to wear a hat and protective clothing when in strong sunshine. Sun beds should be avoided. Patients should be advised to carry out regular self-examination of the skin and report if there are any new lesions and/or changes to skin.
* All oral dosage forms of ciclosporin, including capsules, contain a form of ethanol, a 500mg dose is the equivalent of up to approximately 15 ml beer or 6 ml wine.
* To maintain good oral hygiene, to reduce the risk of gum swelling.

Patient information:Dermatology: [British Association of Dermatologists](https://www.bad.org.uk/pils/ciclosporin/) Patient information leaflets are also available from [the electronic medicines compendium](https://www.medicines.org.uk/emc/search?q=ciclosporin) |
| Pregnancy, paternal exposure and breastfeeding | **All patients should be informed of the risks and benefits of taking this medicine during pregnancy and breastfeeding. The specialist team should be contacted if a patient becomes pregnant or is planning to become pregnant or breastfeed. The specialist should reassume prescribing responsibilities if a patient becomes or wishes to become pregnant.**Pregnancy:BSR guidance on prescribing in pregnancy advises that ciclosporin is compatible throughout pregnancy with monitoring of maternal blood pressure, renal function, blood glucose and drug levels. Regular clinical review and monitoring of maternal whole blood ciclosporin concentration is recommended both during and after pregnancy due to the risk of sub-therapeutic or toxic blood concentrations as a consequence of the pharmacokinetic changes which may be associated with pregnancy. All oral dosage forms of ciclosporin contain a form of ethanol, see [section 7](#seven_pharmaceutical). Information for healthcare professionals: [UK Teratology Information Service (UKTIS)](https://uktis.org/monographs/use-of-ciclosporin-in-pregnancy/) Information for patients and carers: [Best Use of Medicines in Pregnancy (BUMPs)](https://www.medicinesinpregnancy.org/Medicine--pregnancy/Ciclosporin/)Breastfeeding:BSR guidance advises that ciclosporin is compatible with breast milk exposure. There is limited published evidence of safety, but small amounts are found in breast milk. Infants should be monitored for signs of infection or immunosuppression, and infant plasma levels should be monitored if there is any concern about toxicity. All oral dosage forms of ciclosporin contain a form of ethanol, see [section 7](#seven_pharmaceutical). Information for healthcare professionals: [UK Drugs in Lactation Advisory Service](https://www.sps.nhs.uk/medicines/ciclosporin/)Paternal exposure:Based on limited evidence, ciclosporin is compatible with paternal exposure.FertilityThere is limited data on the effect of ciclosporin on human fertility. |
| Specialist contact information and arrangements for referral | Details for contacting specialist must be included on the clinic letter.  |
| Additional information | Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient’s GP or their contact details. |
| References | 1. British National Formulary. Ciclosporin. Accessed via <https://bnf.nice.org.uk/> on 26/10/23.
2. Ciclosporin 100 mg soft capsules (Capimune®). Date of revision of the text 03/2023. Accessed via <https://www.medicines.org.uk/emc/product/695/smpc> on 26/10/23.
3. Ciclosporin 100 mg soft capsules (Deximune®). Date of revision of the text 30/09/23. Accessed via <https://www.medicines.org.uk/emc/product/2613/smpc> on 26/10/23.
4. Ciclosporin soft gelatin capsules (Neoral®). Date of revision of the text 15/09/23. Accessed via <https://www.medicines.org.uk/emc/product/1034/smpc> on 26/10/23.
5. Ciclosporin oral solution (Neoral®). Date of revision of the text 15/09/23. Accessed via <https://www.medicines.org.uk/emc/product/5300/smpc> on 26/10/23.
6. British Society of Rheumatology and British Health Professionals in Rheumatology. 2017. Guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. Accessed via <https://academic.oup.com/rheumatology/article/56/6/865/3053478>.
7. British Society for Rheumatology 2023. Guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids. Accessed via <https://academic.oup.com/rheumatology/article/62/4/e48/6783012>.
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| To be read in conjunction with the following documents | * Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from <https://www.medicinesresources.nhs.uk/shared-care-for-medicines-guidance-a-standard-approach-rmoc.html>
* NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from <https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/>
* General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care>
* NICE NG197: Shared decision making. Last updated June 2021. <https://www.nice.org.uk/guidance/ng197/>.
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