

# SHARED CARE GUIDELINE

Drug: CICLOSPORIN

<b>Contact Details</b> <b>Name:</b> _____ <b>Tel ☎:</b> _____ <b>Location:</b> _____ <b>Date:</b> _____	<b>Patient ID Label</b> <b>Surname:</b> _____ <b>Forename/s:</b> _____ <b>NHS Number:</b> _____ <b>Date of Birth:</b> _____
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<b>Introduction</b>	<p><b>Indication:</b> Treatment of psoriasis and atopic dermatitis.</p> <p><b>Background:</b> Ciclosporin is a cyclic polypeptide with immunosuppressive properties. Studies suggest that ciclosporin inhibits the development of cell-mediated reactions. It appears to block the resting lymphocytes in the G<sub>0</sub> to G<sub>1</sub> phase of the cell cycle, and also inhibits lymphokine production and release, including interleukin 2 (T-cell growth factor). The available evidence suggests that ciclosporin acts specifically and reversibly on lymphocytes. It does not depress haemopoiesis and has no effect on the function of phagocytic cells.</p> <p>Response to treatment may take up to 3 months.</p>
<b>Dose &amp; Administration</b>	<p><b>Psoriasis and atopic dermatitis:</b> starting dose 2.5-5mg/kg/day in two divided doses depending on disease severity and then treated according to response; maximum dose 5mg/kg/day.</p>
<b>Secondary Care Responsibilities</b>	<ol style="list-style-type: none"> <li>1. Confirm the diagnosis.</li> <li>2. Discuss the benefits and side effects of treatment with the patient. Ensure that the patient understands which warning symptoms to report.</li> <li>3. Perform pre-treatment screening:            FBC, LFTs, U&amp;Es, serum creatinine (check twice, 2 weeks apart, to obtain a mean value), fasting lipids, creatinine clearance.            Blood pressure: to be ≤140/90mmHg before treatment on two measurements 2 weeks apart or treat hypertension before starting ciclosporin.</li> <li>4. Provide the patient with a monitoring and dosage record booklet and ensure that the patient knows when and where to attend for monitoring. Encourage the patient to take responsibility for ensuring that results of tests are entered in the monitoring booklet.</li> <li>5. Specify Neoral<sup>®</sup> brand when prescribing ciclosporin.</li> <li>6. Arrange shared care with the patient's GP.</li> <li>7. Review the patient regularly to monitor the patient's response to therapy.</li> <li>8. Request copies of test results for the patient's GP by completing the "copy to" section on the pathology form.</li> <li>9. Advise the GP on dose adjustments and when to stop treatment.</li> <li>10. Ensure that clear backup arrangements exist for GPs to obtain advice.</li> </ol>

<b>Primary Care Responsibilities</b>	<ol style="list-style-type: none"> <li>1. Provide the patient with prescriptions for Ciclosporin (Neoral<sup>®</sup>), available as: Capsules 10mg, 25mg, 50mg and 100mg &amp; Oral solution 100mg/mL. <b>NB:</b> There are differences in bioavailability between different brands of ciclosporin, prescribing should therefore be by brand name.</li> <li>2. Ensure that the patient understands their treatment and which warning symptoms to report.</li> <li>3. Arrange on-going monitoring at the recommended frequencies (see MONITORING below) and ensure that test results are recorded in the monitoring booklet. Request copies of test results for the patient's consultant by completing the "copy to" section on the pathology form.</li> <li>4. Report any adverse events to the consultant or specialist nurse and stop treatment on their advice or immediately if an urgent need arises (see MONITORING below).</li> <li>5. Report any worsening of control of the condition to the consultant or the specialist nurse.</li> </ol>												
<b>Monitoring Required in Primary Care</b>	<ul style="list-style-type: none"> <li>• FBC, LFTs, U&amp;Es, creatinine and urinalysis (plus ESR for Rheumatology patients) weekly for 1 month then monthly until dose and trend stable for 3 months and then 3 monthly.</li> <li>• Fasting lipids 3 monthly.</li> <li>• Blood pressure each time patient attends monitoring clinic.</li> </ul> <p><b>Laboratory adverse events</b></p> <table border="1" data-bbox="403 1048 1465 1384"> <tr> <td colspan="2"><b>STOP Ciclosporin and contact the specialist team if:</b></td> </tr> <tr> <td><b>Creatinine</b></td> <td><b>rises &gt; 30% from baseline</b></td> </tr> <tr> <td><b>Potassium</b></td> <td><b>&gt; 5.5mmol/L</b></td> </tr> <tr> <td><b>Platelets</b></td> <td><b>&lt; 150 x 10<sup>9</sup>/L</b></td> </tr> <tr> <td><b>AST, ALT, Alk Phos</b></td> <td><b>&gt;2 times the upper limit of reference range</b></td> </tr> <tr> <td><b>Lipids</b></td> <td><b>Significant rise in fasting lipids</b></td> </tr> </table>	<b>STOP Ciclosporin and contact the specialist team if:</b>		<b>Creatinine</b>	<b>rises &gt; 30% from baseline</b>	<b>Potassium</b>	<b>&gt; 5.5mmol/L</b>	<b>Platelets</b>	<b>&lt; 150 x 10<sup>9</sup>/L</b>	<b>AST, ALT, Alk Phos</b>	<b>&gt;2 times the upper limit of reference range</b>	<b>Lipids</b>	<b>Significant rise in fasting lipids</b>
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<b>Adverse Effects</b>	<ul style="list-style-type: none"> <li>• Hypertension: If BP <math>\geq</math>140/90mmHg on 2 consecutive occasions 2 weeks apart, treat hypertension before stopping the ciclosporin (note interactions with several antihypertensives). If BP cannot be controlled, <b>STOP</b> ciclosporin and discuss with the specialist team.</li> <li>• Abnormal bruising: Check FBC immediately and <b>STOP</b> ciclosporin. Discuss with the specialist team.</li> <li>• Decreased resistance to infection: <b>STOP</b> ciclosporin if patient is systemically unwell with significant infection.</li> <li>• Benign gingival hyperplasia is relatively common. Patients should be advised on good oral hygiene.</li> <li>• Headache, tremor and paraesthesia are common. If persistent or severe they may reflect toxic levels of ciclosporin. Discuss with the specialist team.</li> </ul>												
<b>Common Drug Interactions</b>	<ul style="list-style-type: none"> <li>• There are numerous drug interactions with ciclosporin, please refer to the BNF and SPC for a detailed description before starting any new drugs.</li> </ul>												

	<ul style="list-style-type: none"> <li>• Patients should be advised to avoid grapefruit or grapefruit juice for 1 hour before or after taking ciclosporin.</li> </ul>
<b>Contra-indications</b>	<ul style="list-style-type: none"> <li>• Uncontrolled hypertension.</li> <li>• Renal failure and liver failure.</li> <li>• Hyperkalaemia.</li> <li>• Suspected systemic infection or sepsis.</li> <li>• Breastfeeding.</li> </ul>
<b>Cautions</b>	<ul style="list-style-type: none"> <li>• Pregnancy – see SPC</li> <li>• Ciclosporin increases the risk of malignancies including skin cancer, patients should be advised to avoid excessive exposure to the sun and to use high factor sunscreens.</li> </ul>
<b>Immunisation</b>	<ul style="list-style-type: none"> <li>• Live vaccines should be avoided.</li> <li>• Annual flu vaccination is recommended.</li> <li>• In patients receiving ciclosporin exposed to chickenpox or shingles, passive immunisation should be carried out using Varicella-Zoster immunoglobulin.</li> </ul>

**This guidance does not replace the SPC's, which should be read in conjunction with this guidance.**