Guideline

Title: Acute Colitis Management

Classification:	Guideline		
Authors Name:	Dr George Macfaul		
Authors Job Title:	Consultant Gastroenterologist		
Authors Division:	Medicine		
Departments/Group this Document applies to:	Patients with suspected or actual colitis		
Approval Group: **Medicine Clinical Improvement Group**		**Date of Approval:**	June 2003
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Unique Identifier: GENM/GL/10	**Status:** Approved	**Version No:** 6.1	
Guideline to be followed by (target staff): Clinicians			
To be read in conjunction with the following documents:			
Are there any eCARE implications? Yes			
CQC Fundamental standards: Regulation 9 – person centred care Regulation 10 – dignity and respect Regulation 11 – Need for consent Regulation 12 – Safe care and treatment Regulation 13 – Safeguarding service users from abuse and improper treatment Regulation 14 – Meeting nutritional and hydration needs Regulation 15 – Premises and equipment			

Disclaimer – For clinical Guideline only

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.
The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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Guideline Statement

The policy has been produced to provide guidance on the clinical management of patients presenting with Acute Colitis. It has been produced following professional consensus. This replaces previous policies on the management of acute colitis.

Objectives

- Safe treatment of patients
- Continuity of patient care

Scope of document

This document applies to any patient within the trust with actual or suspected acute colitis.

1.0 Roles and Responsibilities:

The consultant in charge of the patient care has overall responsibility for ensuring compliance and adherence with the policy. It is the responsibility of all clinical staff to refer to the policy when caring for a patient with Acute colitis

2.0 Recommendation and procedures

- Patients presenting with symptoms of Ulcerative Colitis (with no past Medical History) need sigmoidoscopic evaluation within 24 hours of admission.
- Discuss the disease and associated symptoms, treatment options and monitoring with the patient.
- Stool MC+S including C-Difficile to rule out infection.
- Consider need for gastroenterology bed

For patient with known Ulcerative Colitis or newly diagnosed patients, assess severity of Ulcerative Colitis using **Truelove and Witts criteria.**

3.0 Definition

Acute severe colitis is a medical emergency and is defined by the Truelove and Witts criteria in patients with established or suspected ulcerative colitis.

Bloody stool frequency ≥6/day with one or more of the following:

- Pulse >90bpm
- Temp >37.8oC
- Hb <10.5g/dL
- ESR >30mm/hr (or CRP >45mg/L)

3.1 Table 1. assessment – Mild, Moderate, Severe

	Mild	Moderate	Severe
Bowel movements (no. per day)	Fewer than 4	4-6	6 or more plus at least one of the features of systemic upset (marked with * below)
Blood in stools	No more than small amounts of blood	Between mild and severe	Visible blood
Pyrexia (temperature greater than 37.8°C) *	No	No	Yes
Pulse rate greater than 90 bpm *	No	No	Yes
Anaemia (< 10g/100mL)*	No	No	Yes
Erythrocyte sedimentation rate (mm/hour) *	30 or below	30 or below	Above 30

3.2 Clerking

Admission note should include the following

- Duration of disease
- Duration of symptoms
- Extent of disease (previous notes)
- Date of last relapse
- Current and historical medications
- Document prior azathioprine and anti-TNF exposure
    - Response, duration of response and reason(s) for stopping should be recorded, where applicable
- Recent steroid use (past 12 months)
- Date and result of last colonoscopy
- Physical examination
- Request bloods: FBC, CRP, U+E, pre-biologics screen, stool for C+S and abdominal film
- Request unprepped flexible sigmoidoscopy and speak to endoscopy unit to organise a time for procedure, ideally within first 24 hours of admission (emergency indication)
- Contact gastroenterology registrar on referrals, who will see as a priority.
- Contact ward 8 nurse in charge to prioritise bed
- Registrar to alert consultant gastroenterologist and patient to be reviewed by consultant gastroenterologist within 24 hours of admission.

3.3 Early Management

- Intravenous hydrocortisone 100mg QDS
- Rectal hydrocortisone 100mg in 100ml N/Saline BD
- Dalteparin 5000 units SC once daily

- 3 litres of fluid/day (2 x normal saline, 1 x 5% dextrose), with 60-80mmols KCl/day (hypokalaemia invariable with ASC)
- Review by nutrition team (bleep 1722). Consider TPN for those who are malnourished and considered at high risk for surgery (consultant decision)
- Sips of fluid only
- Stop aminosalicylates
- Antibiotics only where clinical concern for sepsis
- Contact colorectal surgeons to inform them of admission (not necessarily to see, unless moderate-severe abdominal pain, or 'rescue' therapy started).
- Discuss with patient reasons for nil by mouth and expectation that 70% respond to medical therapy
- Identify particular concerns of patient
- Alert IBD nursing team who will provide additional support to patient and liaise with stoma nurses and MDT.
- Daily abdominal examination
- Abdominal XR on admission and discuss with SpR or consultant whether CT scan is indicated
- If mucosal island or dilatation on AXR, repeat after 24 hours. Repeat if re-emergence of tachycardia or temperature.
- Avoid opioids, NSAIDs and hyoscine butylbromide (buscopan). Paracetamol for pain. UC is a mucosal disease and should not be associated with significant abdominal pain. If pain is present, consider possibility of impending perforation - CT scan and surgical review in this instance.
- Stool chart
- Heart rate and temperature four times per day
- Daily FBC, U+E and LFTs
- CRP on admission, day 3 and 5

3.4 Responders (Day 3-5)

Definition: <5 stool per day and absence of rectal bleeding by day 5

- 70% of patients respond to medical therapy
- 50% respond to IV steroids
- In responders, after consultant discussion, convert to oral steroids between day 5-7

Start low fibre diet

Oral prednisolone

- 40mg/day 1 week
- 30mg/day 1 week
- 20mg/day 1 month
- 15mg/day 1 week
- 10mg/day 1 week
- 5mg/day 1 week, then stop

Prednisolone enemas twice daily until bleeding stops, then at night until oral steroids stop (rectal disease only)
Restart mesalazine at maintenance dose
Start azathioprine (2mg/kg/day) unless first attack or previously intolerant of azathioprine

Make sure outpatient appointment is arranged (to see consultant) in clinic within 4 weeks.
Email (SchedulingCentralBooking@mkuh.nhs.uk) and copy (IBDnursing@mkuh.nhs.uk).

3.5 Poor Responders (Day 3)

Definition: Stool frequency >8/day or CRP >45mg/L and stool frequency 3-8 on day 3

Medical Rescue Therapy (commence day 3-5)

- Ciclosporin 2mg/kg iv once daily
- Provided; cholesterol >3mM and Mg2+ >0.5mM
- Oral ciclosporin (Neoral®) 2.5mg/kg twice daily if low Chol/Mg2+
- Infliximab 5mg/kg (ensure pre-biologics screen is sent, no need to wait for results unless specific risk to be considered - discuss with consultant) more appropriate for patients already on azathioprine, or where it is difficult to determine whether the cause of ASC is UC or Crohn's
- Discuss contingency plans (surgery) with patient
- Ask colorectal surgeons to review
- Contact stoma therapist

4.0 Background: Rescue Therapy with Ciclosporin Or Infliximab

Ciclosporin (CsA) is a calcineurin antagonist and potent inhibitor of cell-mediated immunity. Both controlled and uncontrolled studies suggest that CsA is effective 'rescue therapy' for severe UC failing to respond to IV steroids. Early trials used an intravenous dose of 4mg/kg daily. In 2003 a controlled trial confirmed that 2mg/kg was as effective as 4mg/kg. Controlled trials in Crohn's have not shown efficacy for either chronically active disease or for maintenance of remission. The alternative rescue therapy for acute severe colitis is infliximab (IFX). Two controlled trials comparing CsA and IFX have shown both to be similarly effective. The consultant on an individual patient basis makes decisions at an early stage (3-5 days).

4.1 Ciclosporin rescue therapy

4.1.1 Indication

Use of CsA in inflammatory bowel disease is unlicensed. Ciclosporin may be considered for patients with severe UC where IV and rectal hydrocortisone have failed to control symptoms after 3 to 4 days, and in whom additional therapy is required before surgery is considered.

4.1.2 Monitoring

Magnesium

- Measure before treatment
- Hypomagnesaemia is associated with an increased risk of CNS toxicity (seizures)
- Should be >0.5 mmol/L before intravenous infusion

Cholesterol

- Measure before treatment.
- Cholesterol <3.0 is associated with an increase in CNS toxicity (seizures)
- If cholesterol <3.0, use oral ciclosporin (Neoral®)

U&Es
- Monitor before and during treatment
- Dose dependant increases in serum creatinine and urea during the first one to two weeks of treatment may necessitate discontinuation of treatment

LFTs
- Monitor before and during treatment
- Dose reduction on the basis of bilirubin and liver enzymes may be necessary

Blood Ciclosporin Levels
- The therapeutic index for cyclosporin in inflammatory bowel disease has not been clearly identified.
- Measurement of trough ciclosporin levels may however be useful for avoiding toxicity and ensuring adequate absorption.
- Take blood pre-dose in EDTA tube prior to the third or fourth dose
- Aim 100-200ng/mL

BP and pulse:
- Discontinue if hypertension occurs that cannot be controlled by dose reduction or antihypertensives.

4.1.3 Usual Adult Dose
- IV infusion 2mg/kg daily (single dose), given over 6 hours
- Oral dose (following IV therapy) 5mg/day in two divided doses (Neoral®)

4.1.4 Administration
- IV infusion
- Dilute each ml of ciclosporin with 20ml of 5% dextrose or 0.9% sodium chloride
- Administer over 6 hours
- If well tolerated, infusion may be given over 5 hours on day 2 and over 4 hours from day 3
- Due to risk of anaphylaxis, infusions should not be given overnight
- It is recommended that infusions be given after the morning and evening doses of hydrocortisone
- Patients should be closely monitored during the first 30 minutes of the first infusion for signs of anaphylaxis/ hypersensitivity.

4.1.5 Conversion to Oral Therapy and Duration
- Response to IV CsA usually occurs within 2-4 days, based on stool frequency and CRP
- Joint consultant surgical and medical review is appropriate if there is no response after 2 days
- Assuming a response, convert to oral ciclosporin 2.5mg/kg twice daily
- On discharge, continue standard reducing course of prednisolone and ciclosporin 2.5mg/kg twice daily
- Review in outpatients in 2 weeks
- Measure CsA levels, blood pressure, electrolytes, and creatinine
- Prescribe azathioprine 50-100mg/day to start when the dose of prednisolone is in the last week of 20mg/d (i.e. a month before it stops)
- Review in 4 weeks and recheck blood tests (FBC, CRP, U&Es, LFTs)

- Aim to continue CsA, if tolerated, for 3 months and then stop (no tapering necessary)

4.1.6 Cautions and Contraindications

- Known hypersensitivity to ciclosporin
- Renal impairment
- Uncontrolled hypertension
- Uncontrolled infections
- Malignancy of any kind

4.1.7 Pregnancy

- As the safety of CsA in human pregnancy has not been fully established it should only be given in pregnancy if the benefits outweigh any potential risk. In these circumstances, best discuss with specialist colleagues. Ciclosporin has not been shown to be teratogenic in animal studies.

4.1.8 Breastfeeding

- Ciclosporin passes into breast milk and mothers receiving treatment with CsA should not therefore breast-feed their infants.

4.1.9 Interactions

- Ciprofloxacin
- Other immune suppressants except corticosteroids (increased risk of infection /malignancy)
- Grapefruit juice increases blood levels of CsA and increases risk of toxicity. Should not be consumed less than one hour before or after an oral dose.
- For other interactions see BNF

4.1.10 Potential Side Effects

- Seizures (associated with the intravenous formulation at high dose)
- Renal toxicity
- Hypertension
- Liver toxicity
- Hyperkalaemia
- Increased susceptibility to infections
- Anaphylaxis (usually to polyethoxylated castor oil in the injection)
- Hyperlipidaemia
- Irritation at injection site, care of venflon is essential.
- Flushing, tremor, fatigue
- Gastrointestinal disturbances
- Paraesthesiae (burning sensation in hands and feet)
- Gingival hyperplasia and hypertrichosis (long term treatment only)

5.0 Infliximab Rescue Therapy

Infliximab (IFX) is licensed for use at 5mg/kg induction week 0, 2 and 6.

In patients with extensive haemorrhagic colitis who have not responded to treatment, a higher dose of infliximab (10mg/kg loading, or a second 5mg/kg at 24-48 hours) can be considered at the discretion of the clinician. This would be an immediate rescue treatment and not an individual funding request.

Maintenance therapy will usually be continued for 12 months at least, but alternative strategies may be considered on a case by case basis. This will be a Consultant/MDT decision.

Checking drug trough levels between second and third infusion can be helpful in guiding optimal dose (or at earlier stage if partial response or early response followed by clinical deterioration. Accelerated dosing has been suggested by uncontrolled studies but not confirmed by meta-analysis. A RCT to evaluate this strategy is in progress (2019, Oxford, Amsterdam).

In a 2016 open label randomised, non-inferiority trial conducted in the UK, 270 patients with ASC were treated with either CsA or IFX at standard dosing. No significant difference was observed in the early or late colectomy rate between both groups after 3 years of follow-up (41% IFX vs. 48% CsA, p=0.224).

6.0 Acute Severe Crohn's disease

As above, except no rectal steroids unless distal colonic disease present.

Add metronidazole 500mg IV TDS

Caution prescribing steroids, especially in patients where sepsis, perforation or bowel obstruction is clinically suspected or if there is a history of penetrating disease - discuss with consultant gastroenterologist.

5-aminosalicylates are not effective agents for disease modification in Crohn's disease and should not usually be prescribed for this indication.

7.0 Statement of evidence/references

Oxford gut doctors (with permission), oxford translational gastroenterology unit
Infliximab versus ciclosporin for steroid-resistant acute severe ulcerative colitis (CONSTRUCT): a mixed method, open-label, pragmatic randomised trial. Williams JG, Alam MF, Alrubaiy L, Arnott I, Clement C, Cohen D, Gordon JN, Hawthorne AB, Hilton M, Hutchings HA, Jawhari AU, Longo M, Mansfield J, Morgan JM, Rapport F, Seagrove AC, Sebastian S, Shaw I, Travis SP, Watkins A. Lancet Gastroenterol Hepatol 2016.

https://www.ecco-ibd.eu/index.php/publications/ecco-guidelines
www.e-guide.ecco-ibd.eu

Acknowledgements
With thanks to Professor Simon Travis, Professor Satish Keshav and the Oxford IBD team.

8.0 Governance

8.1 Document review history

Version	Review Date	Reviewed By	Changes made
1.0	June 2003	Dr. Lanzon-Miller	New policy
2.0	October 2007	Dr. Madhotra	Reviewed and updated
3.0	February 2009	Dr. Madhotra	Reviewed and updated
4.0	August 2011	Tracey Shaul	Updates
4.0	August 2011	Quynh-Anh Nguyen	Pharmacy changes made
4.0	August 2011	Dr. Macfaul	Reviewed and updated to new template and amendments to the policy
5.0	July 2015	Lianne Lewis	Minor Changes
6.0	August 2018	Dr. Lahiff	Reviewed and updated
6.1	September, 2020	Dr. Macfaul Christina Theophile-Clarke	Reviewed and updated Reviewed and minor changes updated

8.2 Consultation History

Stakeholder Name	Area of Expertise	Date Sent	Date Received	Comments	Endorsed Yes/No
Dr Lanzon-Miller	Consultant Gastroenterology	06/2003	06/2003	New Policy	
Dr. Madhotra	Consultant Gastroenterologist	10/2007	10/2007	Reviewed and updated	
Dr. Madhotra	Consultant Gastroenterologist	02/2009	02/2009	Reviewed and updated	
Dr. Macfaul	Consultant Gastroenterologist	08/2011	08/2011	Reviewed and updated	Updates
Dr Lanzon-Miller	Consultant Gastroenterologist	08/2011	08/2011	updates	
Dr. Lahiff	Consultant Gastroenterologist	08/2018	08/2018	Reviewed and updated	
Dr. Macfaul	Consultant Gastroenterologist	09/2020	09/2020	Reviewed and updated	

8.3 Audit and monitoring

How will compliance of this Guideline be evidenced?.

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board

8.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

Equality Impact Assessment			
Division	Medicine	Department	Gastroenterology
Person completing the EqIA	Christina Theopile-Clarke	Contact No.	
Others involved:		Date of assessment:	
Existing policy/service	Yes	New policy/service	

Will patients, carers, the public or staff be affected by the policy/service?	Yes
If staff, how many/which groups will be affected?	Patients with suspected or actual colitis

Protected characteristic	Any impact?	Comments
Age	~~YES~~ NO	Positive impact as the policy aims to recognise diversity, promote inclusion and fair treatment for patients and staff
Disability	~~YES~~ NO	
Gender reassignment	~~YES~~ NO	
Marriage and civil partnership	~~YES~~ NO	
Pregnancy and maternity	~~YES~~ NO	
Race	~~YES~~ NO	
Religion or belief	~~YES~~ NO	
Sex	~~YES~~ NO	
Sexual orientation	~~YES~~ NO	

What consultation method(s) have you carried out?
face-to-face meetings, PRG, etc
How are the changes/amendments to the policies/services communicated?
email, meetings, intranet post
What future actions need to be taken to overcome any barriers or discrimination?

What?	Who will lead this?	Date of completion	Resources needed
Review date of EqIA			

Appendix 1: CICLOSPORIN BLOOD MONITORING PROTOCOL

Equipment needed:

- 3ml EDTA FBC sample (purple bottle).
- Request 'ciclosporin' levels on E-Care, mark 'URGENT' and inform the 'send away section' in pathology on x3620 that you are bringing up a sample that needs to be couriered to Harefield. Then personally take sample to path. Lab. Ask person receiving sample to courier it to Harefield Hospital.

Background Information:

- Monitor 12-hour trough levels.
- Sample has a maximum stability of 18 days.
- Store sample at room temperature or in fridge.
- Weekday blood samples must be at Harefield Hospital by 1pm and will need couriering if same day result is needed.
- Opening Hours: Monday- Friday 08.45hrs – 5pm. Weekends and Bank Holidays: 10am-1pm.
- Weekend blood samples must be couriered to Harefield Hospital Main reception by 11am.
- Harefield lab have a 4-hour turnaround time for samples.
- Results are faxed FAO Linda Roberts in Pathology ext. 5234 (as soon as the results are received, they are put on E-Care. However, results received outside core hours i.e. after 5pm or at the weekend will not be actioned until the next morning on a weekday, or a Monday morning if it is the weekend. If you require the result urgently you can phone Harefield directly on 01895 828 570. Until the result is authorised it is not visible on the system. If a trough level is abnormally high, Linda will ring the relevant Gastro team), a hard copy is posted to the MK biochemistry laboratory, but you can also ring the Harefield lab directly for a verbal result on 01895 828 570. Harefield lab will call your bleep if you make it clear on the request form that you would like them to contact you directly.
- **Trough level between 100-200ng/ml** for ulcerative colitis (not toxic until level over 500ng/ml if renal function is normal).
- Contacts at Harefield: Head of Service: Neil Leaver, Deputy: Jane Tiller. 01895 828 570

Procedure:

- Once decision has been made to give cyclosporin, give patient information leaflet (available from IBD ANP on bleep 1807) and obtain form from pharmacy for patient and consultant gastroenterologist to sign as cyclosporin is off licence for ulcerative colitis. Pharmacy will not dispense drug until this has been completed and returned to them.

- Prior to first dose of cyclosporin bloods need to be checked for magnesium, potassium, cholesterol, renal function and blood pressure needs checking.

- Oral dose calculated at 5mg/kg **for total daily dose. Then halve the dose** to be given BD at 1000hrs and 2200hrs.

- Wait 3 days before taking 1st trough level (as it takes 3 days before equilibrating through the tissues). This sample should be taken prior to the administration of the morning dose of cyclosporin. The first result is often higher than expected but you do not need to change the dose at this point.

- Recheck levels again 2 days later.

- Monitoring thereafter according to clinical need or at week 1, 2, 4 then monthly.

- If requesting a night dose bleeding, send a fax to: 01895 828901 and send sample in the morning.

- If sample needs to be sent out of hours i.e. over a weekend you MUST inform Harefield on Friday on 01895 828570.

Medical emergencies can be discussed by our Consultant with the Consultant Head of Service, Neil Leaver, via Harefield switchboard on air call pager. In his absence Harefield switchboard will contact Jane Tiller via air call.

Appendix 2: CYCLOSPORIN PATIENT INFORMATION LEAFLET

Milton Keynes University Hospital NHS
NHS Foundation Trust

Department of Gastroenterology

Inflammatory Bowel Disease

Medicine information

CICLOSPORIN

Why am I being treated with this medicine?

Ciclosporin (cyclosporin, also known as Neoral) is used to attempt to induce remission in acute severe ulcerative colitis. It is used in hospital when patients have not responded to standard treatment for inflammatory bowel disease, including steroids. The use of Ciclosporin has been demonstrated to reduce the need for a surgical operation to remove the large bowel (called a colectomy). It is also used in other groups of patients including those with rheumatoid arthritis, psoriasis and with organ transplantation.

How does Ciclosporin work?

Ciclosporin suppresses inflammation by dampening down your body's immune system. The immune response is what caused the inflammation and ulceration of your bowel.

What are other names for these medications?

Ciclosporin [cyclosporin], is occasionally referred to by the brand name which is Neoral.

How much will I need to take and how often?

Your dose will be calculated depending on your weight and rounded up to the nearest capsule size, your health care professional will advise you how much you should take. The total dose is usually 5 mg/Kg per day, given in divided doses about 12 hours apart. The dose may be adjusted according to response and blood levels of the drug.

Some patients in hospital may be started on Ciclosporin given intravenously (into a vein) at first, and then convert to oral medication. The dose may be adjusted according to its clinical response, Ciclosporin blood levels, blood pressure and kidney function. You will have regular blood tests during your treatment which will check the level of the medication in your blood; this will help to make sure you are on the correct dose. You will need to take your medication every day.

Neoral (Ciclosporin) comes as a gel-filled capsule and is available in four different strengths – 100mg (grey), 50mg (white) 25mg (grey) and 10mg (white). Neoral is also available as a liquid. Neoral is taken twice a day. Ideally the two doses should be taken 12 hours apart at 10.00am and 10.00pm. The times should be fixed as much as possible, to ensure accurate blood levels are obtained, as this will enable appropriate blood levels to be achieved. It is therefore very important that you don't take your dose of Cyclosporin until *after* blood levels have been taken.

How do I take this medication?

The capsules should be taken with a mouthful of water and swallowed whole. Ciclosporin should be taken on an empty stomach, or at least 1 hour before, or 2 hours after a meal (as food affects its absorption). *Whole grapefruit and grapefruit juice should be avoided* in the hour before you take the capsules as they can increase Ciclosporin levels in the blood. It is important to check the label on your tablet container so you know which strength tablets you have been given as this will affect the number of tablets you need to take.

How long do they take to work?

The benefits of Ciclosporin are often seen quite quickly (within days).

How long will I need to take this medication for?

If you tolerate this then you will be on this medication usually for 3 months, during this period your clinician may start you on alternative therapies to maintain clinical remission, so that the Ciclosporin can be weaned off and eventually stopped. Do not stop taking your medication unless your health professional tells you to, even if you feel well.

What do I do if I miss a dose?

If you forget a dose, take it as soon as you remember as long as it is not almost time for your next dose, as you need to leave 12 hours in-between doses. Do not double up on your next dose, just continue taking the tablets as directed but make a note of it in your diary and remember to tell your doctor on your next visit. If you take too much, then contact your health professional as soon as possible.

Can I take other medicines and alcohol with this drug?

Ciclosporin is compatible with most other medicines but always remind your health professional that you are taking Ciclosporin if a new medication is being prescribed for you. You will also need to tell the Pharmacist if you buy any "over the counter medicines" that you are taking Ciclosporin.

Certain medications interact with Ciclosporin, these include non-steroidal anti-inflammatory drugs (e.g. Ibuprofen), St John's Wart and erythromycin. Alcohol can be taken in moderation, however for general health reasons it is best to remain within the Department of Health advised limits. High level of alcohol intake can seriously affect blood levels of the drug.

What checks will I need?

Ciclosporin can raise your blood pressure and affect the kidneys. We recommend that your blood pressure, blood count and kidney function are checked every 2 days for the 1st week. Your treatment monitoring will be managed by your hospital team or shared between the hospital and GP.

You will be monitored closely whilst you are taking this medicine. You will need regularly blood tests for three months. This test will check the level of the medication in your blood, this will help to make sure you are on the correct dose.

Can I have immunisations whilst I am on this medication?

The Department of Health advises you should have an annual flu vaccine, please book one at your local GP practice. It may be unsafe to have certain vaccines, you should not have any live vaccines, as these contain live viruses such as: Polio, yellow fever, rubella, MMR, BCG. However, you may be able to have the inactivated polio vaccine. It is important that you check with your health professional prior to having any vaccines.

Will I need to take any special precautions while I am taking this medication?

Your body's resistance to infection is likely to be reduced whilst taking Ciclosporin. Therefore, you should avoid contact with people who have an obvious infection. You should contact your health professional if you begin to feel unwell and think you may have caught an infection. You can potentially become seriously unwell from the viruses that cause chickenpox, measles, shingles, and pneumococcal disease. If you come into contact with anyone who has these conditions tell your health professional as soon as possible.

Will this medication affect fertility or pregnancy?

Inform your health professional if you are thinking about pregnancy or are pregnant. You should avoid becoming pregnant while you are taking Ciclosporin. Make sure you have discussed with your doctor which types of contraception are suitable for you and your partner. If you do have any questions, then discuss them with your health professional.

Can I breastfeed whilst taking this medication?

You should not breast feed if you are taking Ciclosporin.

What are the possible side effects of taking this medication?

All medicines can cause unwanted side effects. Some people taking Ciclosporin will experience unwanted side effects initially, however not everyone will get them and as your body adjusts to the medication the side effects may improve over a few weeks. The monitoring of your blood will enable early identification of some adverse effects.

Most will not suffer any of these known side effects. If you do experience any of these symptoms, then contact your health professional.

- Nausea and tiredness are common, but wear off within weeks
- Increased hair growth. This can be removed or coloured.
- Slightly enlarged or sore gums. If problematic see your dentist.
- Tremor or shakiness of the hands.
- High blood pressure, kidney dysfunction and liver inflammation. All are monitored for as they can be reversed by stopping/reducing dose.
- Increased risk of infections. Please inform a member of your inflammatory bowel disease team if you come into contact with chickenpox, as you may need preventative treatment.
- Headache and abdominal cramps can occur in the early stages.
- Hot, burning, numbness in the hands and feet. This normally lessens after a couple of weeks.
- Metallic taste in the mouth
- Painful periods or lack of periods.

You will need to speak to your health professional before you make any changes to how you take your medication, or dosage. Do not stop taking your medication until you have spoken to your health professional.

Keep all medicines out of the reach of children. Never give any medicine prescribed for you to anyone else. It may harm them even if their symptoms are the same as yours.