Shared Care Protocol

Shared Care Guideline Shared Care Guideline for Subcutaneous Methotrexate for Rheumatological Conditions		Reference Number
Version: 1.3	**Replaces: Version 1.2**	**Issue date: 21/07/2023**
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Date approved by Commissioners:	**Date approved by NHS GMIC Stockport: 28/08/2023**	
	Review Date: *August 2025*	

Please complete all sections

1. Name of Drug, Brand Name, Form and Strength	Methotrexate Injection pre-filled auto-injector pen. Must prescribe by brand in accordance with local guidance.
2. Licensed Indications	Subcutaneous methotrexate is licensed to treat adults with rheumatoid arthritis and is also widely used to treat other inflammatory arthritides and connective tissue diseases.
3. Criteria for shared care	Prescribing responsibility will only be transferred when: - • Treatment is for a specified rheumatological and gastroenterological indication. • Treatment has been initiated and established by the secondary care specialist. • The patient's initial reaction to and progress on the drug is satisfactory. • The GP has agreed in writing in each individual case that shared care is appropriate. • The patient's general physical, mental, and social circumstances are such that he/she would benefit from shared care arrangements. Subcutaneous Methotrexate may be considered for primary care prescribing if all the

	following apply: - • The patient /carer/representative self-administers. • The hospital provides adequate training to patients on administration and provides support if problems arise with self-administration. • The ICB/hospital provides a robust mechanism for the disposal of cytotoxic sharps • Practices are not encouraged to administer subcutaneous methotrexate.
4. Patients excluded from shared care	• Patient does not consent to shared care. • Patient does not meet criteria for shared care. • Patient unable to self-administer methotrexate. Primary health care teams/district nurses are not encouraged to administer subcutaneous methotrexate. • Appropriate mechanism for safe transport and removal of cytotoxic waste/sharps from patients homes not in place.
5. Therapeutic use & background	Methotrexate is an anti-metabolite cytotoxic drug which inhibits DNA synthesis and cellular replication. It belongs to the group of DMARDs alongside gold, hydroxychloroquine, azathioprine, leflunomide, and sulfasalazine. Parenteral methotrexate can: - • Ensure the maximum bioavailability. • Reduce symptomatic side effects for some patients, thus increases in the therapeutic dose are better tolerated. • Extend the time that disease is controlled before expensive anti-TNF therapies need to be introduced. • Improve the patient's quality of life and satisfaction with treatment.
6. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	• Hypersensitivity to the active substance or to any of the excipients. • Severe liver impairment. • Alcohol abuse. • Severe renal impairment (creatinine clearance less than 30 ml/min). • Pre-existing significant underlying haematological disorder, such as bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anaemia. • Serious untreated acute or chronic infections such as tuberculosis. • Ulcers of the oral cavity and known active gastrointestinal ulcer disease.
7. Prescribing in pregnancy and lactation	This drug cannot be prescribed in the pregnant or breastfeeding patient. Following administration to a man or woman, conception should be avoided by using an effective contraception method for at least 3 months after finished course. Methotrexate cannot be recommended in breastfeeding because of theoretical risks and insufficient outcome data
8. Dosage regimen for continuing care	***Route of administration*** Subcutaneous
	Preparations available: Methotrexate as 'pre-filled pen', 'pre-filled syringe' or 'pre-filled injector'. Various strengths available as per BNF.
	Please prescribe: 7.5 - 25mg ONCE WEEKLY by brand according to hospital instructions (The initial dose may be 5-15mg once weekly, increasing by 2.5mg-5mg every 2-6 weeks until the disease has stabilised). In Gastroenterology initial doses may be 25mg once weekly, reducing to 15mg maintenance. . Treatment will be initiated in secondary care with prescription, review and blood monitoring completed in secondary care for the first 3 months of therapy.

	Is titration required	**Yes**	
	The specialist will initiate treatment and provide THREE months therapy and titrate the dose until stable. Maintenance doses range from 7.5mg to 25mg subcutaneously ONCE weekly. **MHRA Warning this is a ONCE WEEKLY dose.** Fatalities have been reported due to prescribing and dispensing errors. If changing from oral methotrexate to parenteral administration a reduction of the dose may be required due to the variable bioavailability of methotrexate after oral administration. **NB. All dose adjustments will be the responsibility of the initiating specialist unless directions have been specified in the medical letter to the GP.**		
	Adjunctive treatment regime: Folic acid 5mg ONCE weekly also given but may be given more frequently if necessary (usually 3 days after methotrexate). Folic acid reduces the toxic effects of methotrexate. Folic acid can be given any day as long as it is not on the same day as methotrexate		
	Conditions requiring dose reduction: Lower doses should be used in the frail elderly or those with renal or hepatic disease. Methotrexate should be used with caution in patients with impaired renal function. The dose should be adjusted as follows as per the Renal Drug Database. Dose reductions recommended when eGFR/GFR < 60mL/min. Treatment not recommended when eGFR/GFR < 30mL/min. Initiating Consultant will review renal function prior to initial treatment. Significant changes in renal function during treatment should be alerted to Rheumatology or Gastroenterology team as outlined in section 10.		
	Usual response time: Response to treatment can be expected after approximately 6 - 12 weeks.		
	Duration of treatment: ongoing		
	Treatment to be terminated by: Healthcare professional in consultation with Rheumatology or Gastroenterology team		
9.Drug Interactions ***For a comprehensive list consult the BNF or Summary of Product Characteristics***	The following drugs must <u>not</u> be prescribed without consultation with the specialist: • **<u>Trimethoprim or co-trimoxazole</u> must be avoided in patients taking methotrexate due to increased risk of pancytopenia (increased antifolate effect). Must avoid trimethoprim for 3 months after taking methotrexate.** • Avoid concomitant use of cytotoxics and clozapine as increased risk of agranulocytosis. • Retinoids as increased risk of hepatotoxicity and increased plasma levels.		

	• Ciclosporin or leflunomide- risk of toxicity. • Levetiracetam - plasma concentration of methotrexate possibly increased by levetiracetam. • Nitrous oxide and pyrimethamine - antifolate effect of methotrexate increased. The following drugs may be prescribed with caution: • Caution with phenytoin potential to increase antifolate effect. • NSAIDs, aspirin and penicillin all reduce the tubular excretion of methotrexate and thereby enhance toxicity. • Aminophylline - methotrexate possibly increases plasma concentration of aminophylline. • Ciprofloxacin - excretion of methotrexate possibly reduced by ciprofloxacin. • Excess alcohol should be avoided (or limit to max. 6 units per week). • Caution with drugs with potential hepatotoxic or nephrotoxic effects.
10. Adverse drug reactions *For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF*	**Specialist to detail below the action to be taken upon occurrence of a particular adverse event as appropriate. Most serious toxicity is seen with long-term use and may therefore present first to GPs.**

Adverse event System – symptom/sign	**Action to be taken** Include whether drug should be stopped prior to contacting secondary care specialist	**By whom**
WBC<3.5x10^9/L Neutrophils <1.6x10^9/L Platelets <140x10^9/L eosinophils >0.5 x 10^9/L	Withhold until discussion with Rheumatology or Gastroenterology team.	GP
MCV>105 fl	Check B12, folate and TSH. If abnormal treat any underlying abnormality. If normal, discuss with Rheumatology or Gastroenterology	GP
ALT and/or AST >100 units/L or increases from baseline greater than 2 x upper limit of normal	Withhold until discussion with Rheumatology or Gastroenterology team as risk of liver cirrhosis	GP
Declining renal function Creatinine >30% above baseline and/or calculated GFR <60ml/min	Withhold until discussion with Rheumatology or Gastroenterology team as risk of renal failure	GP
Unexplained fall in serum albumin	Withhold until discussion with Rheumatology or Gastroenterology	GP
New or increasing dyspnoea and/or dry cough	Withhold and discuss urgently with rheumatology Or Gastroenterology team as risk of interstitial	GP
Severe sore throat, abnormal bruising	Withhold and carry out urgent FBC as risk of bone marrow suppression	GP

	Suspected infection requiring antibiotics	Withhold temporarily until infection cleared	GP

The patient should be advised to report any of the following signs or symptoms to their GP without delay:

- Severe skin rash that causes blistering
- Persistent cough, pain or difficulty breathing or become breathless
- Skin rash and fever with swollen glands
- Sore throat, fever, chills, or achiness
- Severe allergic reaction (anaphylactic reaction)
- Stomatitis as this may be first sign of gastro-intestinal toxicity.

Other important co morbidities (e.g. Chickenpox exposure). Include advice on management and prevention and who will be responsible for this in each case:

- Pneumococcal polysaccharide vaccine (PPV) also known as PPV23, and annual flu vaccine should be given.
- Passive immunisation should be carried out using Varicella zoster immunoglobulin (VZIG) in non-immune patients if exposed to chicken pox or shingles.
- During infection methotrexate should be temporarily discontinued until the patient has recovered from the infection.
- From 1st September 2023 patients receiving methotrexate at a dose greater than 20mg each week, who cannot receive the live shingles vaccine, will become eligible to receive two doses of Shingrix (non-live) from 50 years of age. Please refer to UK Health Security Agency Vaccine update issue 340.

Any adverse reaction to a black triangle drug or serious reaction to an established drug should be reported to the MHRA via the "Yellow Card" scheme.

11.Baseline investigations

Chest X-ray
FBC
U&E
LFTs
Pulmonary function tests (depending on clinical indication)
BP
Height and weight
Virology

12. Ongoing monitoring requirements to be undertaken by GP

Is monitoring required?	**Yes** – as well as responding to absolute values, it is also relevant to observe trends in results e.g., gradual decreases in WBC or albumin, or climbing liver enzymes			
Monitoring	**Frequency**	**Results**	**Action**	**By whom**

	FBC, U&E, Creatinine, LFT, Albumin, CRP and Plasma viscosity	Every two weeks until on a stable dose for 6 weeks. *(note that GP monitoring and prescribing will commence from 12 weeks following initiation). Then monthly for 3 months. **Thereafter every <u>12</u> weeks**. (More frequent monitoring is appropriate in patients at higher risk of toxicity.) Dose increases should be monitored every 2 weeks until on stable dose for 6 weeks then revert to previous schedule	See Section 10: Adverse drug reactions above.	See Section 10: Adverse drug reactions above.	GP
13. Pharmaceutical aspects	Store below 25 °C. Keep the pre-filled pens in the outer carton in order to protect from light. Patients should be encouraged to use the same community pharmacy. (Note from CCG pharmacist GPs to prescribe monthly quantities and ensure monitoring is up to date before issuing. Consider using acute or variable repeat field for methotrexate s/c inj to reduce the risk of errors and over ordering). **Disposal of Sharps** If the methotrexate is to be administered in the patient's home cytotoxic sharps bins (purple top) need to be supplied as required by the Stepping Hill Hospital. This may be at clinic, via the hospital pharmacy or the Outpatient Pharmacy Shop. Patients should be advised to return their boxes for disposal and replacement when full or approximately every 3-6 months. Full sharps bins must be fully sealed and then may be returned to the Stepping Hill Hospital Outpatient Pharmacy Shop. Patients should be informed that under no circumstances should cytotoxic sharps or bins be disposed in household waste.				
14. Responsibilities of initiating specialist	• Initiate treatment, prescribe, and monitor bloods for 12 weeks or until dose and blood monitoring is stable for 6 weeks (no shorter than 12 weeks). • Undertake baseline monitoring. • Issues associated with self-administration (post training) as per section 3 above. • Dose adjustments and advise GP as necessary. • Monitor patient's initial reaction to and ongoing progress on the drug. • Ensure that the patient has an adequate supply of medication until GP supply can be arranged. • Patients will be considered suitable for transfer to GP prescribing ONLY when they meet the criteria listed in section 3 above. • The consultant team will write formally to the GP to request shared care using the Shared Care Agreement Form (Appendix 1) which must be fully completed and returned as indicated. • Responsibility for prescribing and monitoring of methotrexate will be transferred to the GP once the GP has agreed via signing copies of the Shared Care Agreement Form (Appendix 1). • Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted				

	by the GP. • Provide GP with diagnosis, relevant clinical information and baseline results, treatment to date and treatment plan, individualised blood monitoring regimen (as appropriate) and duration of treatment before consultant review. • Provide GP with details of outpatient consultations, ideally within 14 days of seeing the patient or inform GP if the patient does not attend appointment. • Provide GP with advice on when to stop this drug. • Act upon communication from the GP in a timely manner. • Provide patient with relevant drug information to enable Informed consent to therapy. • Provide patient with relevant drug information to enable understanding of potential side effects and appropriate action. • Provide patient with relevant drug information to enable understanding of the role of monitoring. • Provide patient with monitoring booklet where appropriate. • Be available to provide patient specific advice and support to GPs as necessary (see rheumatology helpline number below).
15. Responsibilities of the GP	• Continue treatment as directed by the specialist. • Act upon communication from the specialist in a timely manner. • Ensure no drug interactions with concomitant medicines. • To monitor and prescribe in collaboration with the specialist according to this protocol. • To ensure that blood monitoring is carried out once responsibility transferred from secondary care. • To inform Rheumatology or Gastroenterology team if patient repeatedly does not attend for routine blood monitoring. • To ensure that the monitoring and dosage record is kept up to date (if applicable). • To undertake vaccination as directed by the initiating consultant, the BNF or Green Book. • Symptoms or results are appropriately actioned, recorded and communicated to secondary care when necessary. • Formally reply to the consultant's request to shared care within 14 days of receipt, using the shared care agreement forms (Appendix 1). NB the GP should only agree to the transfer of prescribing if all details of the form have been completed. • If the GP does not feel it is appropriate to take on the prescribing, then the prescribing responsibilities will remain with the specialist. The GP should indicate the reason for declining. • Enter a READ code (8BM5.00) on to the patient record to highlight the existence of shared care for the patient • Undertake more frequent tests if there is evidence of clinical deterioration, abnormal results, or other risk factors. Contact consultant team for advice on monitoring in these circumstances if required. • Check all monitoring results prior to issuing a repeat prescription to ensure it is safe to do so. • Monitor the patient's general wellbeing. • Inform the consultant immediately if a patient has become pregnant or is planning to become pregnant for treatment options to be considered. • Notify the consultant of any circumstances that may preclude the use of methotrexate for example, the use of illicit drugs or contraindications to treatment. • Seek urgent advice from secondary care if: ➢ Toxicity is suspected. ➢ Non-compliance is suspected. ➢ The GP feels a dose change is required.

<table>
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There is marked deterioration in the patient's condition.
The GP feels the patient is not benefiting from the treatment.

The shared care agreement will cease to exist, and prescribing responsibility will return to secondary care, where:

The clinical situation deteriorates such that the shared care criterion of stability is not achieved.
The clinical situation requires a major change in therapy.
The patient is a risk to self or others.
GP feels it to be in the best stated clinical interest of the patient for prescribing responsibility to transfer back to the Consultant. The Consultant will accept such a transfer within a timeframe appropriate to the clinical circumstances.

There must be discussion between the consultant team and GP on this matter and agreement from the consultant team to take back full prescribing responsibility for the treatment of the patient. The consultant team should be given 14 days' notice in which to take back prescribing responsibilities from primary care.

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<tr><td>16. Responsibilities of the patient</td><td colspan="4">

To take medication as directed by the prescriber, or to contact the GP if not taking medication (including folic acid).
To attend hospital and GP clinic appointments, bring monitoring booklet (if issued).
Failure to attend will result in medication being stopped (on specialist advice).
To report adverse effects to their Specialist or GP.
Should be aware that they must not be taking oral methotrexate whilst being treated with subcutaneous methotrexate.
Ensure safe storage of methotrexate and cytotoxic waste.
To seal and return cytotoxic bins to the hospital pharmacy or Outpatient Pharmacy Shop and obtain replacements every 3 to 6 months or as needed.
To avoid self-medicating with NSAIDs or aspirin.

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<tr><td>17.Additional Responsibilities
e.g. Failure of patient to attend for monitoring, Intolerance of drugs, Monitoring parameters outside acceptable range, Treatment failure, Communication failure</td><td>List any special considerations

Failure to attend for monitoring</td><td>Action required

No further prescriptions to be issued</td><td>By whom

GP</td><td>Date</td></tr>
<tr><td>18. Supporting documentation</td><td colspan="4">The prescription must be accompanied by a patient information leaflet. (Available from http://www.medicines.org.uk/emc OR http://www.mhra.gov.uk/spc-pil/)</td></tr>
<tr><td>19. Patient monitoring booklet
(may not be applicable for all drugs)</td><td colspan="4">The patient must receive a monitoring booklet from the specialist upon initiation of treatment. The patient must bring this booklet to all specialist and GP appointments where it will be updated by the health professional conducting the appointment. The patient must also produce the booklet to any health professional involved in other aspects of their care e.g., pharmacists and dentists.</td></tr>
<tr><td>20. Shared care agreement form</td><td colspan="4">Attached below.</td></tr>
<tr><td>21. Contact details</td><td colspan="4">Secondary care contact information
If stopping medication or needing advice, please contact: Rheumatology Helpline Contact number: 0161-419-4250. Fax: 0161-419-5548</td></tr>
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	C**ommissioner contact information** Name: Jacqueline Coleman (Secondary Care Interface Pharmacist) Email: jacqueline.coleman@nhs.net Contact number: 0161 426 9910 Organisation: NHS GMIC Stockport
	Lead author contact information Rebecca Heaton (Rheumatology Specialist Pharmacist) Email: rebecca.heaton@stockport.nhs.uk. Contact number:0161 419-5202

Version Details	Change details	Date
1.1 update following expiry	Remove reference to live vaccines and methotrexate	02/11/2021
1.2 additions	1. version control table 2. Enter Trust/specialist responsibility for issues with self-administration post training	02/02/2022
1.3 additions	1. Section 10 information shingles vaccine for over 50s from 1st September 2023. 2. Changed references to Stockport CCG to NHS GMIC Stockport 3. Changed CCG logo to GMIC partnership logo 4. Changed link to GMICS Stockport website in GP letter to https://www.stockportpracticehub.co.uk/practicehub/medicines-optimisation-guidance/shared-care-guidelines/	21/07/2023

Appendix 1 – Shared care request/acceptance form

RE: Patient Name, date of birth, address, telephone number

Rheumatology/Gastroenterology Shared Care Agreement Specialist Request
IMPORTANT: ACTION NEEDED

Dear Dr,

This patient is suitable for treatment with a medication which has been accepted for shared care according to the Greater Manchester Medicines Management Group protocol.

A copy of the approved shared care protocol for this drug can be found on the NHS GMIC Stockport website at https://www.stockportpracticehub.co.uk/practicehub/medicines-optimisation-guidance/shared-care-guidelines/

The patient fulfils the criteria for shared care and I am therefore requesting your agreement to share the care of this patient. Pre-treatment investigations have been undertaken as per the shared care agreement and the patient is now suitable to be commenced on the treatment below.

Please see the corresponding clinic letter (sent on the same date as this agreement request) for details of the medication including the titration period if appropriate. The patient has been informed regarding the risks and benefits of treatment, the baseline tests conducted, the need for monitoring and how this will be arranged and the roles of the Rheumatology Specialist team, GP and the patient in shared care. The patient has understood and is satisfied with this shared care arrangement at this time.

Please return this response form within the next 14 days via fax to 0161 419 5231.

Thank you

The Rheumatology/Gastroenterology Team

Response Form (to be completed by the GP and returned to the fax number above)
Dear Dr_____,
I have received your request for shared care of the above patient who has been advised to start _____ as requested by their rheumatology consultant.

A: I am willing to undertake shared care for this patient as set out in the protocol
B: I wish to discuss this request with you
C: I am unable to undertake shared care of this patient.
If unable to undertake shared care, please state why:

GP Signature:

Date:

GP address/practice stamp
Yours sincerely

Appendix 2 - Summary

Shared Care Guideline Summary:
Subcutaneous Methotrexate for the treatment of Rheumatological Conditions

Drug	Methotrexate subcutaneous injection
Indication	Methotrexate is indicated for the treatment of active rheumatoid arthritis or severe psoriatic arthritis
Overview	Subcutaneous methotrexate is licensed to treat adults with rheumatoid arthritis and is also widely used to treat other inflammatory arthritides and connective tissue diseases.
Specialist's Responsibilities	**Initial investigations:** • Chest X-ray, FBC, U&E, LFTs, BP, Height, and weight **Initial regimen:** • Methotrexate as per appropriate patient prescription, new starters usually 7.5mg, switch in therapy – dose as appropriate for individual patient. Dose range 7.5-25mg weekly. • plus Folic acid 5mg ONCE weekly orally **Clinical monitoring:** • CRP and Plasma viscosity. **Safety monitoring:** • Every two weeks until on a stable dose for 6 weeks. • Then monthly for 3 months • Thereafter every 8-12 weeks. (More frequent monitoring is appropriate in patients at higher risk of toxicity.) • After dose increases: every 2 weeks until on stable dose for 6 weeks then revert back to previous schedule **Prescribing duration:** Started by hospital and supplied by hospital for the initial 3 months of treatment, thereafter, transferred to the GP (local commissioning arrangements may vary). To advise GP on when to stop treatment **Prescribing details:** Initiated by specialist, prescribed and monitored by the specialist for the first 3 months and then care transferred over to the GP (local commissioning arrangements may vary). To stop the drug or provide information to the GP on when to stop the drug **Documentation:** Patients will only be transferred to the GP once the GP has agreed via signing copies of the shared care agreement form. Provide GP with diagnosis, relevant clinical information, treatment plan, duration of treatment within 14 days of seeing the patient or inform the GP if the patient does not attend.
GP's Responsibilities	**Maintenance prescription:** Prescribe and monitor methotrexate 3 months after initiation in accordance with the specialist's recommendations (local commissioning arrangements may vary). **Clinical monitoring:**

Monitoring	Frequency	Results	Action
FBC, U&E, Creatinine LFT, Albumin, CRP and Plasma viscosity	Every two weeks until on a stable dose for 6 weeks. Then monthly for 3 months Thereafter every 8 - 12 weeks. (More frequent monitoring is appropriate in patients at higher risk of toxicity.)	See Section 10: Adverse drug reactions above	See Section 10: Adverse drug reactions above

	Dose increases should be monitored every 2 weeks until on stable dose for 6 weeks then revert **back** to previous schedule		

Safety monitoring: See table below – adverse events. To report to and seek advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment.

Duration of treatment: ongoing. Specialist to advice on when treatment should be stopped.

Documentation: Formally reply to the consultant's request to shared care within 14 days of receipt, using the shared care agreement forms.

Adverse Events

Adverse Events	Action
WBC<3.5x109/L Neutrophils <1.6x109/L Platelets <140x109/L eosinophils >0.5 x 109/L	Withhold until discussion with rheumatology team.
MCV>105 fl	Check B12, folate and TSH. If abnormal treat any underlying abnormality. If normal, discuss with rheumatology team.
ALT and/or AST >100 units/L	Withhold until discussion with rheumatology team as risk of liver cirrhosis.
Declining renal function Creatinine >30% above baseline and/or calculated GFR <60	Withhold until discussion with rheumatology team as risk of renal failure.
Unexplained fall in serum albumin	Withhold until discussion with rheumatology team.
New or increasing dyspnoea and/or dry cough	Withhold and discuss urgently with rheumatology team as risk of interstitial pneumonitis.
Severe sore throat, abnormal bruising	Withhold and carry out urgent FBC as risk of bone marrow suppression
Suspected infection requiring antibiotics	Withhold temporarily until infection cleared

Contra-indications Cautions Drug Interactions

Please refer to the BNF and/or SPC for information

- This drug cannot be prescribed in the pregnant or breastfeeding patient.
- hypersensitivity to the active substance or to any of the excipients
- severe liver impairment or alcohol abuse,
- severe renal impairment (creatinine clearance less than 30 ml/min.
- pre-existing blood dyscrasias, such as bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anaemia,
- serious, acute or chronic infections such as tuberculosis, HIV or other immunodeficiency syndromes,
- ulcers of the oral cavity and known active gastrointestinal ulcer disease,
- concurrent vaccination with live vaccines.

Other Information

Folic acid 5mg ONCE weekly also given but may be given more frequently if necessary (usually 3 days after methotrexate).
Pneumovax and annual flu vaccine should be given.

Contact Details

GP Name: *[insert text here]*
Practice Address: *[insert text here]*
Practice Telephone: *[insert text here]*