

METHOTREXATE POLICY

Care of Patients who are taking Methotrexate in Low Immunosuppressant Doses (e.g. weekly oral / s/c / or i/m doses)

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'Out of date policy documents must not be relied upon'

Approval Committee	Version	Issue Date	Review Date	Document Author
Drug & Therapeutics Committee	1	March 2011	March 2013	Paul Ramsden Senior Specialist Pharmacist Medication Risk Reduction
Medicines Governance Committee	2	December 2013	December 2016	Paul Ramsden Senior Specialist Pharmacist Medication Risk Reduction
MGC & D&TC	3	March 2015	March 2018	Paul Ramsden Senior Specialist Pharmacist Medication Risk Reduction Anita Balestrini Clinical Services Manager (Acting)

Version Control

Version	Date	Author	Section	Principle Amendment Changes
2	December 2013	Paul Ramsden Senior Specialist Pharmacist Medication Risk Reduction	Whole policy 2) vii) 6) 7)	Amended to refer to other routes of administration as well as oral Amended Rheumatology contact details Added note re need for contraception Amend wording to say folic acid should (rather than may) be prescribed. Amended to comply with Document Control
3	March 2015	Paul Ramsden Anita Balestrini		Addition of 2vii Appendix iii and iv - Consent checklists added for all specialties (courtesy of Rheumatology department) Appendix v - Addition of Patient Information leaflet for gastroenterology 5ii(4) Encouraging patients to inform community pharmacist that they are on MTX 12(v) Patient to be given an NPSA booklet by the Pharmacist (if the prescriber does not)

Low dose Methotrexate is usually given ONCE weekly on the same day each week

1) Purpose and intended use of this policy

- i) *National Patient Safety Agency (NPSA)* alert numbers 3 and 13 require Trusts to implement actions to increase the safety of once weekly oral methotrexate
- ii) **A significant number of deaths have resulted from incorrect use of this medicine.**
- iii) This policy is intended to specify how to use low dose methotrexate safely in patients taking the drug who are treated at RBCH
- iv) It is intended to be used by all staff caring for methotrexate patients
- v) **It should be used in conjunction with policies and shared-care guidelines in use by specialist departments that routinely initiate and supervise low dose methotrexate treatment. Advice may be sought from these departments if necessary (see below)**

2) General Information

- i) The usual dose range is 7.5mg to 25mg weekly
- ii) **Only 2.5mg** tablets are stocked at this Trust
- iii) It is used to treat various inflammatory disorders including active inflammatory arthritis, especially Rheumatoid Arthritis and Psoriatic Arthritis, Psoriasis and Crohn's disease.
- iv) Methotrexate may also be used to treat certain malignant disorders but this use is not covered by this policy
- v) Treatment is initiated by a specialist experienced in use of methotrexate and continuing care and prescribing may then be transferred to the patient's G.P. under appropriate supervision by the specialist
- vi) All patients should be issued with an **NPSA information, dosage and monitoring booklet** as part of the counselling and consent process, by the department initiating methotrexate treatment. Current dose and monitoring details should be documented in the booklet and the patient should show it to any health care professional caring for them
- vii) A 'Consent Checklist' has been provided for all specialities (courtesy of the Rheumatology Department) to aid the consent process (see Appendix II)
- viii) Further advice regarding use of methotrexate may be obtained by reference to the individual departments' policies or shared-care guidelines for initiation and maintenance of low dose methotrexate or by reference to the relevant specialist consultant or nurse practitioner
- ix) A patient information leaflet is available for Gastroenterology patients (see Appendix V)
- x) The current nurse practitioners contact details are as follows:
 - **Rheumatology** (Sue Farndon) ext. 5302
 - **Dermatology** (Sian Allen) ext. 5471
 - **Gastroenterology** (Heather Johnson) ext. 4191

3) Monitoring

- i) On admission, check patient's relevant tests i.e. haematological, renal/hepatic function and check that there have been no significant changes or abnormalities compared with the most recent results on eCamis or documented in the patient-held information and monitoring booklet
- ii) Other more specific tests e.g, CRP, ESR/PV, PIIINP may also be appropriate.
- iii) If any concerns, seek the advice of the appropriate specialist (see "signs and symptoms of toxicity" below)
- iv) On discharge, ensure that the patient has sufficient forms for continuing monitoring tests

4) Signs and Symptoms of Toxicity

- i) Methotrexate should be withheld and advice sought urgently from the appropriate specialist in the event of concerns about the following signs or symptoms (especially if new or worsening):

- Gastro-intestinal symptoms: Nausea, vomiting, anorexia, diarrhoea, oral ulceration
 - Stomatitis
 - Haematological toxicity: Sore throat, severe mouth ulcers, fever, abnormal bruising, abnormal FBC (WBC < 3.5, Neutrophils < 2, Platelets < 120), increased MCV, unexplained fall in albumin
 - Hepatotoxicity: Raised ALT/ AST
 - Pulmonary toxicity: Shortness of breath, non-productive cough (request chest x-ray)
 - Renal: worsening renal function
 - Rash
- ii) See Appendix 1 below for advice on managing overdoses or serious interactions

5) Interactions

- i) Always consider possible interactions with prescribed and over-the-counter (OTC) medication as a potential cause of problems
- ii) Clinically significant interactions that may increase methotrexate toxicity include:
- NSAIDs (e.g. ibuprofen, diclofenac), aspirin, co-trimoxazole, trimethoprim, penicillins, ciclosporin, corticosteroids, probenecid, acitretin
 - Although it may be appropriate to prescribe some of the above e.g. NSAIDs, aspirin, corticosteroids etc. to patients on methotrexate, interaction with them should always be considered as a potential cause of complications
 - **Important Note: Interactions with Trimethoprim and Co-trimoxazole are particularly hazardous and these antibiotics MUST NEVER be given with weekly methotrexate.**
 - (1) If necessary, advice should be sought from microbiology to identify an alternative antibiotic
 - (2) These antibiotics should be documented in the allergy / intolerance section of the drug chart with a note that the patient is on methotrexate
 - (3) The importance of avoiding these antibiotics should be reiterated to the patient
 - (4) Patients should be encouraged to alert anyone who may be involved in their care of the need to avoid this interaction and to request that a warning is added to their records for example as an allergy.
- iii) Patients on methotrexate should not be given live vaccines
- iv) See BNF for further details of interactions

6) Pregnancy and Breastfeeding

- i) Women who are pregnant, attempting to become pregnant or breastfeeding should not use methotrexate
- ii) Contraception is mandatory in both men and women of childbearing age and must be continued for at least 6 months after stopping treatment

7) Folic Acid

- i) This should be prescribed to reduce side-effects e.g. gastro-intestinal
- ii) The dose is 5mg once weekly, or more often
- iii) It should not be given on the same day as methotrexate

8) Prescribing (General Points)

- i) **Important Note:** Always check routine tests (see monitoring above) to ensure no contraindications before prescribing methotrexate
- ii) Prescriptions and any discharge information must be clear, in indelible ink and include the form, strength, dose and directions in full
- iii) Repeat prescriptions are not allowed for methotrexate
- iv) Prescriptions should be for an appropriate duration between monitoring tests
- v) Results of monitoring tests and the patient's dose must be reviewed before a new prescription is written

9) Prescribing for Outpatients

- i) Refer to individual departments' policies or shared-care guidelines for initiation and maintenance of low dose methotrexate

- vi) The patient's own supply should be used wherever possible for in-patients
 - Pharmacy staff must ensure that the correct current dose is on the label
 - If no medication has been brought in, Pharmacy staff should check whether any can be brought in
 - If necessary an appropriate quantity should be supplied- this supply should be kept to a minimum e.g. one week at a time, although a larger supply may be made if considered necessary by the pharmacist
 - Supplies should never last longer than the date of the next due monitoring test

13) Administration

- i) Methotrexate is given ONCE weekly on the same day each week
- ii) Use the patient's own supply where possible or ask Pharmacy staff to supply. Methotrexate 2.5mg tablets are not stocked on any wards (and 10mg not stocked at all)
- iii) Refer to Trust Administration of Medicines and Patient Identification Policies for general requirements
- iv) Before administering the dose:
 - Check the patient's identity carefully against the details on the drug chart and the details on the methotrexate container label
 - Check the patient's name, name of medicine, dose, strength of tablets (if on oral) and timing of dose
 - Confirm dose details with the patient, including that the dose is due at that time and is as expected e.g. number of tablets. Ask to see the patient's NPSA booklet (see general information)
 - Check for potential interactions with any newly prescribed medication (see section above)
- v) Clearly and promptly record on the drug chart that the dose has been given

Appendix I

Advice on Managing Methotrexate Overdoses and Serious Interactions

Methotrexate toxicity appears potentially more likely with repeated excess therapeutic dosing than with single acute ingestions. This is probably because of saturation of the active absorption mechanism. Daily ingestion of weekly doses (10 to 20 mg) for between 6 and 23 days has resulted in death, from pancytopenia, sepsis, pneumonia or multiple organ failure.

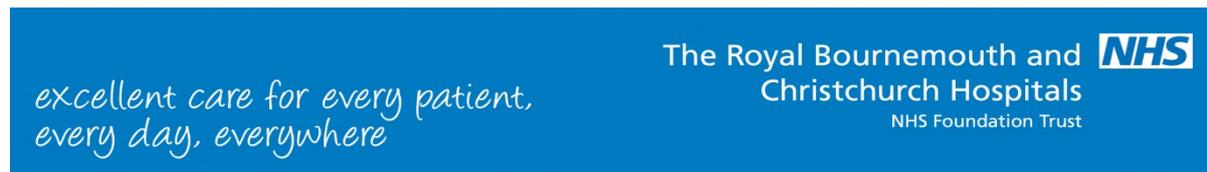
1. Management of a suspected methotrexate overdose:

- 1.1 Contact the poisons centre on: 0844 892 0111, for advice on management.
- 1.2 Patients who ingest **a single additional daily dose** should be advised to omit their next dose
Monitor for toxicity as in 2.2 and 2.3 below.

2. If a serious drug interaction has occurred e.g. with concomitant trimethoprim or co-trimoxazole then:

- 2.1 Stop the interacting drug, and if necessary, prescribe an alternative
- 2.2 Inform the patient, their doctors and nurses of the interaction and to monitor regularly for the following signs of methotrexate toxicity:
 - Vomiting
 - Diarrhoea
 - Mucositis
 - Oropharyngeal ulceration
 - Haemorrhagic enteritis
 - Erythematous rashes.
- 2.3 Check the patient's FBC, U&Es, LFTs.
The full blood count may be normal initially but pancytopenia may develop over the next 7 to 12 days.
Repeat blood tests at weekly intervals, if asymptomatic, for 4 weeks after the overdose.
Note that hepatotoxicity, renal failure and interstitial pneumonitis are recognised late complications.
- 2.4 Be aware that hypoalbuminaemia, folate deficiency and concomitant use of non-steroidal anti-inflammatory drugs predispose to methotrexate toxicity.

This information has been adapted from the Toxbase methotrexate monograph last updated 01/2011 accessed via www.toxbase.org.uk on 31/01/11



Rheumatology Department

CONSENT TO TREATMENT WITH ORAL METHOTREXATE

I

Hospital ID confirm that:

1.	I have been given a copy of the NPSA Methotrexate monitoring booklet.	
2.	I have read the information in the booklet and had the opportunity to ask questions.	
3.	I have had a chest x-ray within the last 6 months.	

I understand that:

4.	I should bring my NPSA booklet to each clinic visit so that the most recent blood test result can be entered and the dose update if necessary. If I live outside the area and have the blood test at my GP surgery, I need to get the results for each test written in the book.	
5.	All the Methotrexate tablets I am prescribed as my weekly dose are taken together on the same day each week.	
6.	I should check that I have only been prescribed 2.5mg tablets of Methotrexate (not 10mg which MUST be returned to the pharmacy).	
7.	Regular blood tests are necessary to check on the liver and the blood count. I must have these blood tests according to the instructions given by the rheumatology clinic. If I develop a severe sore throat or bleeding / bruising I need to report this to my GP or contact the rheumatology clinic (01202 705302) urgently.	
8.	Methotrexate can occasionally affect the lungs. If I develop a dry cough or become breathless while taking Methotrexate I need to report this to my GP or contact the rheumatology clinic (01202 705302) urgently.	
9.	Methotrexate can interact with other drugs. When I am given a new prescription or buy medication from a high street pharmacy, I need to check they are safe to take with Methotrexate. I should not take TRIMETHOPRIM or SEPTRIN (antibiotics usually given for urinary tract infections) with Methotrexate. If I am prescribed low dose aspirin or anti-inflammatory medications (eg. Ibuprofen) I may continue to take these while taking Methotrexate	
10.	If I have any severe illness eg. bad diarrhoea and vomiting, I should avoid taking Methotrexate until I am better.	
11.	I should not drink more than 7 units of alcohol per week while taking Methotrexate. (7 glasses of wine / 3 and a half pints of beer / 7 small spirits).	
12.	I should not father a child / become pregnant while taking Methotrexate. I should stop Methotrexate 6 months before trying for a family.	
13.	I should not have any live vaccines (eg. yellow fever) while taking Methotrexate. The seasonal flu vaccine and pneumonia vaccine are safe and recommended.	

Signed:

Date:

Appendix III

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The Royal Bournemouth and 
Christchurch Hospitals
NHS Foundation Trust

Gastroenterology Department

CONSENT TO TREATMENT WITH METHOTREXATE

I

Hospital ID confirm that:

1.	I have been given a copy of the RBCH and or the NPSA Methotrexate monitoring booklet.	
2.	I have read the information in the booklet and had the opportunity to ask questions.	
3.	I have had a chest x-ray within the last 6-12 months.	
4.	I have had a recent respiratory function test at the Royal Bournemouth Hospital.	

I understand that:

5.	The Methotrexate dose will be administered as a once a week dose on the visit.	
6.	Three monthly blood tests are necessary to check on the liver and the blood count. I must have these blood tests according to the instructions given by the gastroenterology clinic. If I develop a severe sore throat or bleeding / bruising I need to report this to my GP or contact the gastroenterology clinic (01202 704191) urgently.	
7.	Methotrexate can occasionally affect the lungs. If I develop a dry cough or become breathless while taking Methotrexate I need to report this to my GP or contact the gastroenterology clinic (01202 704191) urgently.	
8.	Methotrexate can interact with other drugs. When I am given a new prescription or buy medication from a high street pharmacy, I need to check they are safe to take with Methotrexate. I should not take TRIMETHOPRIM or SEPTIN (antibiotics usually given for urinary tract infections) with Methotrexate. If I am prescribed low dose aspirin or anti-inflammatory medications (eg. Ibuprofen) I may continue to take these while taking Methotrexate	
9.	I should not drink more than 7 units of alcohol per week while having Methotrexate therapy (7 glasses of wine / 3 and a half pints of beer / 7 small spirits).	
10.	I should not father a child / become pregnant while taking Methotrexate. I should stop Methotrexate 6 months before trying for a family.	
11.	I should not have any live vaccines (eg. yellow fever) while taking Methotrexate. The seasonal flu vaccine and pneumonia vaccine are safe and recommended.	

Signed:

Date:

Appendix IV

Dermatology Department

CONSENT TO TREATMENT WITH ORAL METHOTREXATE

I

Hospital ID confirm that:

1.	I have been given a copy of the NPSA Methotrexate monitoring booklet.	
2.	I have read the information in the booklet and had the opportunity to ask questions.	
3.	I have had a chest x-ray within the last 6 months.	

I understand that:

4.	I should bring my NPSA booklet to each clinic visit so that the most recent blood test result can be entered and the dose update if necessary. If I live outside the area and have the blood test at my GP surgery, I need to get the results for each test written in the book.	
5a.	If treatment is by Methotrexate Injection this will be administered once a week at clinic visit.	
5b.	All the Methotrexate tablets I am prescribed as my weekly dose are taken together on the same day each week.	
6.	If I am having treatment with Methotrexate tablets, I should check that I have only been prescribed the 2.5mg strength (NOT 10mg which MUST be returned to the pharmacy).	
7.	Regular blood tests are necessary to check on the liver and the blood count. I must have these blood tests according to the instructions given by the gastroenterology clinic. If I develop a severe sore throat or bleeding / bruising I need to report this to my GP or contact the dermatology clinic (01202 705471) urgently.	
8.	Methotrexate can occasionally affect the lungs. If I develop a dry cough or become breathless while taking Methotrexate I need to report this to my GP or contact the dermatology clinic (01202 705471) urgently.	
9.	Methotrexate can interact with other drugs. When I am given a new prescription or buy medication from a high street pharmacy, I need to check they are safe to take with Methotrexate. I should not take TRIMETHOPRIM or SEPTRIN (antibiotics usually given for urinary tract infections) with Methotrexate. If I am prescribed low dose aspirin or anti-inflammatory medications (eg. Ibuprofen) I may continue to take these while taking Methotrexate	
10.	If I have any severe illness eg. bad diarrhoea and vomiting, I should avoid taking Methotrexate until I am better.	
11.	I should not drink more than 7 units of alcohol per week while having Methotrexate therapy (7 glasses of wine / 3 and a half pints of beer / 7 small spirits).	
12.	I should not father a child / become pregnant while taking Methotrexate. I should stop Methotrexate 6 months before trying for a family.	
13.	I should not have any live vaccines (eg. yellow fever) while taking Methotrexate. The seasonal flu vaccine and pneumonia vaccine are safe and recommended.	
14.	Sharps Bins – I will return these to clinic for destruction.	

Signed:

Date:

Appendix IV

Does Methotrexate affect fertility or pregnancy?

You should not take Methotrexate when pregnant as it can harm an unborn baby. While taking Methotrexate and for six months after stopping it, both men and women should take contraceptive precautions. If you are planning a family or become pregnant while taking Methotrexate, you should discuss this with your doctor as soon as possible.

May I drink alcohol while taking Methotrexate?

Alcohol may interact with Methotrexate but small amounts are unlikely to be a problem.

If you have any concerns about your treatment you should discuss these with your doctor.

Our Vision

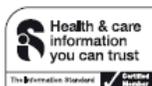
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Please contact the author if you would like details
of the evidence in the production of this leaflet.

We can supply this information in other formats,
in larger print, on audiotape, or have it translated for you.

Please call the Patient Advice and Liaison Service (PALS)
on **01202 704886**, text or email **pals@RBCH.nhs.uk** for further advice.



Author: **Heather Johnson** Date: **February 2015**
Version: **Two** Review date: **February 2018** Ref: **1125/10**

Website: www.rbch.nhs.uk ■ **Tel:** 01202 303626

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The Royal Bournemouth and
Christchurch Hospitals 
NHS Foundation Trust

Methotrexate

Patient Information

Website: www.rbch.nhs.uk ■ **Tel:** 01202 303626

Why do I take Methotrexate?

Methotrexate is used in the treatment of Crohn's Disease and more recently for ulcerative colitis. Methotrexate affects the immune system (the body's own defence system). It reduces the activity of the immune system and is always used with care. It can be used for the treatment of active disease and for preventing recurrence of the disease in the longer term.

When do I take Methotrexate and what dose?

Methotrexate is usually given by injection once weekly for the first 16 weeks in our day unit. The initial dosage is 25mg. On week 16 our nurses will show you how to perform the injection yourself. You will then continue weekly injections of 15mg methotrexate at home. Occasionally methotrexate is given in tablet form once a week. These have a 2.5mg strength and you may be asked to take between four and ten tablets together once a week only.

How long will Methotrexate take to work?

Methotrexate does not work immediately, it may be 4 to 12 weeks before you notice any benefit.

Do I need any special checks while on Methotrexate?

Baseline respiratory function and a chest x-ray will be done before starting treatment. Methotrexate can affect the blood count and can sometimes cause liver problems. These may be picked up at an early stage by regular checks on your blood. The Specialist Nurse or doctor will arrange these checks, weekly for the first eight weeks then every three months thereafter. This is very important and you must not take Methotrexate unless you are having regular checks. In some unusual cases a biopsy of the liver may be required before starting or during treatment with Methotrexate.

What are the possible side effects?

All drugs can cause side effects, although most patients never have them.

The most common side effects are tiredness, which can last for 24 hours after the injection. Feeling sick (nausea), diarrhoea, mouth ulcers and skin rashes. Taking Methotrexate can make you more likely to develop infections. If you develop a sore throat or other infection, a fever, develop unexplained bruising or bleeding, or become jaundiced or you develop any new symptoms after starting Methotrexate, you should report to your Hospital Consultant, Specialist Nurse or doctor.

The least common side effects are inflammation of the lung or of the liver. If you become breathless, you should see your doctor immediately. Your regular blood tests will look for signs of Methotrexate affecting your liver.

Most doctors prescribe folic acid tablets to patients who are taking Methotrexate as this can reduce the likelihood of side effects. Folic acid is also taken once weekly, three days after the Methotrexate.

If you have not had chickenpox but come into contact with someone with chicken-pox or shingles, you should report to your doctor immediately as you may need special treatment. If you develop chicken-pox or shingles you should report to your doctor.

Can I take other medicines along with Methotrexate

Most drugs can be taken safely. However, if you start any new drug you should tell the doctor that you are taking Methotrexate. You should not take "over the counter" medicines without discussing things first with your doctor. Special care is needed with anti-inflammatory drugs. Sulphonamides and Trimethoprim antibiotics must NOT be taken with Methotrexate.

Can I have immunisation injections while on Methotrexate?

You should avoid immunisation injections which involve live vaccines such as polio and rubella (German measles). Flu vaccines are safe and should be encouraged.

Consultation Process

Version	Date	Author	Level of Consultation
1	March 2011	Paul Ramsden	D&TC Rheumatologists (via Dr N Hopkinson) Gastroenterologists (via Dr S Weaver), Dermatologists (via Dr I Pearson) Haematologists (via Dr S Killick)
2	December 2013	Paul Ramsden	MGC, plus as above (not D&TC)
3	March 2015	Paul Ramsden Anita Balestrini	MGC, D&TC Gastroenterology Nurse (Heather Johnson) Dermatology Nurse (Sian Allen) Rheumatology Nurse (Sue Farndon)

EQUALITY IMPACT ASSESSMENT – SCREENING FORM

1. Title of document/service for assessment	Methotrexate Policy
2. Date of assessment	March, 2015
3. Date for review	March, 2018
4. Directorate/Service	Trust-wide
5. Approval Committee	MGC

	Yes/No	Rationale
6. Does the document/service affect one group less or more favourably than another on the basis of:		
• Race	No	
• Gender (including transgender)	No	
• Religion or belief	No	
• Sexual orientation, to include heterosexual, lesbian, gay and bisexual people	No	
• Age	No	
• Disability – learning disabilities, physical disabilities, sensory impairment and mental health issues	No	
• Marriage and Civil Partnership	No	
• Pregnancy and Maternity	No	
7. Does this document affect an individual's human rights?	No	
8. If you have identified potential discrimination, are the exceptions valid, legal and/or justified?	N/A	

9. If the answers to any of the above questions is 'yes' then:	Tick	Rationale
Demonstrate that such a disadvantage or advantage can be justified or is valid		
Adjust the policy to remove disadvantage identified or better promote equality		
If neither of the above possible, submit to Diversity Committee for review.		

10. Screener(s)

Print name: Paul Ramsden

11. Date Policy approved by Committee	March, 2015
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12. Upon completion of the screening and approval by Committee, this document should be uploaded to papertrail.