## Policy for the safe use of oral methotrexate

### Policy Checklist

<table>
<thead>
<tr>
<th>Name of Policy:</th>
<th>Policy for the safe use of oral methotrexate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose of Policy:</td>
<td>To ensure compliance with the requirements of the National Patient Safety Agency (NPSA) alert relating to oral methotrexate</td>
</tr>
<tr>
<td>Directorate responsible for Policy</td>
<td>Acute Services, Children’s and Young Peoples Services, Mental Health and Disability, Older People and Primary Care</td>
</tr>
<tr>
<td>Name &amp; Title of Author:</td>
<td>Jillian Redpath, Medicines Governance Pharmacist</td>
</tr>
<tr>
<td>Does this meet criteria of a Policy?</td>
<td>Yes</td>
</tr>
<tr>
<td>Staff side consultation?</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Equality Screened by:</td>
<td>Jillian Redpath, Medicines Governance Pharmacist</td>
</tr>
<tr>
<td>Date Policy submitted to Policy Committee:</td>
<td>24 September 2012</td>
</tr>
<tr>
<td>Members of Policy Scrutiny Committee in Attendance:</td>
<td>Vivienne Toal, Head of Employee Engagement &amp; Relations (Chair), Anne Brennan, Senior Manager, Medical Directorate, Claire Graham, Head of Corporate Records (for Siobhan Hanna), Marita Magennis, Head of Social Work and Social Care Governance, Danny McKeVitt, Head of Specialist Estate Services, Stephen McNally, Director of Finance &amp; Procurement, Trevor Burns, Fire Safety Manager, (Specialist Estates), (for Danny McKeVitt)</td>
</tr>
<tr>
<td>Policy Approved/Rejected/Amended</td>
<td>Approved</td>
</tr>
<tr>
<td>Policy Implementation Plan included?</td>
<td>Yes – Memorandum via e-mail</td>
</tr>
<tr>
<td>Any other comments:</td>
<td>N/A</td>
</tr>
<tr>
<td>Date presented to SMT:</td>
<td>Director of Acute Services</td>
</tr>
<tr>
<td>Date received by Employee Engagement &amp; Relations for database/Intranet/Internet:</td>
<td>September 2012</td>
</tr>
<tr>
<td>Date for further review:</td>
<td>September 2014</td>
</tr>
</tbody>
</table>
| Title | Title: Policy for the safe use of oral methotrexate  
Version: 1.0  
Reference number/document name: |
|---|---|
Description of Amendments(s)/Previous Policy or Version: |
| Originator | Name of Author: Jillian Redpath  
Title: Medicines Governance Pharmacist |
| RM/Policy Committee & SMT approval | Referred for approval by: Anita Carroll  
Date of Referral:  
RM/Policy Committee Approval:  
SMT approval (Date) |
| Circulation | Issue Date:  
Circulated By:  
Issued To: |
| Review | Review Date: September 2014  
Responsibility of (Name): Jillian Redpath  
Title: Medicines Governance Pharmacist |
1.0 Introduction

Methotrexate is a folic acid antagonist and is classified as an antimetabolite cytotoxic immunosuppressant agent. It is indicated for the treatment of cancers such as leukaemias, lymphomas and a number of solid tumours. It is also used to treat non-malignant conditions such as rheumatoid arthritis; it is also used for the treatment of severe psoriasis unresponsive or intolerant to conventional therapy.

When used for non-malignant indications such as psoriasis and rheumatoid arthritis, methotrexate is administered usually ONCE a week and the maximum dose is usually 25mg. Medication incidents have occurred with oral methotrexate because:

- weekly doses have been taken on a daily basis
- 10mg tablets have been confused with 2.5mg tablets
- higher doses for malignant conditions have been confused with doses for non-malignant conditions
- ‘Monday’ has been misread as ‘morning’
- Signs and symptoms of oral methotrexate toxicity such as breathlessness, dry persistent cough, vomiting or diarrhoea may be misinterpreted as for example, infection.

This policy supports the Trusts’ implementation of DHSSPS ‘Recommendations to improve the safe use of oral methotrexate in primary and secondary care in Northern Ireland(revised) (2005)’\(^1\) and NPSA Patient Safety Alert ‘Improving compliance with oral methotrexate guidelines (2006)’.\(^2\)

2.0 Aim

To promote safe prescribing, administration, dispensing and monitoring of patients receiving oral methotrexate.
3.0 Policy

3.1 Prescribing oral methotrexate

3.1.1 Information on the risks and benefits of oral methotrexate must be given to the patient when considering initiation of methotrexate treatment, as per Trust policy. Confirmation of patient understanding and consent must be sought.

3.1.2 Baseline tests should be conducted, results recorded, monitoring schedule explained, and a patient-held monitoring booklet issued as specified in the regional Shared Care Guideline for oral methotrexate\(^3\).

3.1.3 The prescribed dose for methotrexate in non-malignant conditions is usually once a week and must specify the day of the week on which the dose is to be taken. Monday should be avoided.

3.1.4 Prescribers and other health care practitioners as appropriate must carefully advise the patient of the dose and frequency of oral methotrexate and of the number of tablets or quantity of liquid they require to make up their dose. NB 2.5mg is the only strength of tablet used and 10mg/5ml is the only strength of liquid used.

3.1.5 For in-patients when weekly oral methotrexate is prescribed, the prescriber must put a line through the six days of the week in the administration section of the Kardex when a dose must not be administered and a box around the day of the week when the dose is to be administered. The frequency ‘once a week’ and the day of the week on which the dose is to be taken must also be specified in the special instructions/additional information section of the Kardex.
3.1.6 Discharge and outpatient prescriptions and discharge summary information must state the dose, frequency ‘once a week’, formulation and day the oral methotrexate is to be taken. 'As directed' must not be used as a dosage instruction.

3.1.7 Patients should also be prescribed folic acid 5mg once a week, to be taken one or two days after methotrexate in accordance with the Shared Care Guideline.

3.1.8 Full medication reviews, conducted where possible by pharmacists, must be undertaken on admission and discharge and at review clinic appointments.

3.1.9 All prescribing, monitoring and administration requirements should be recorded in the patient’s notes.

3.1.10 Information on medicines interacting with methotrexate is available from the BNF, SPC and Medicines information. In particular, concomitant trimethoprim or co-trimoxazole must not be prescribed due to the risk of pancytopenia.

3.1.11 When discharging patients newly initiated on methotrexate, prescribers should follow the agreed regional Shared Care Guideline.

3.2 Monitoring oral methotrexate

3.2.1 Patients receiving oral methotrexate should be monitored to identify possible signs of toxicity. Be aware of patients who attend with symptoms
such as breathlessness, dry persistent cough, vomiting or diarrhoea as these may be signs of oral methotrexate toxicity or intolerance.

3.2.2 The patient’s current monitoring schedule on admission should be confirmed and existing test results checked as appropriate.

3.2.3 For inpatients, the monitoring schedule for the admission should be agreed taking account of the pre-admission monitoring schedule and current clinical condition.

3.2.4 For outpatients and patients in the community, the regional Shared Care Guideline for oral methotrexate should be referred to for information on monitoring.³

3.3 Electronic prescribing and dispensing systems

3.3.1 Electronic prescribing and dispensing systems must only offer methotrexate 2.5mg tablets or 10mg/5ml liquid as available strengths.

3.3.2 If an incorrect dose, strength or frequency has been entered into an electronic system, it should be removed. The correct information must be added and an annotation made that an incorrect entry had been made.

3.4 Dispensing oral methotrexate

3.4.1 Wards/departments other than Pharmacy must not hold routine stocks of methotrexate tablets.

3.4.2 Methotrexate 2.5mg tablets only must be stocked in Pharmacy and dispensed. Each patient must receive written information about the strength of oral methotrexate dispensed either using an information card (Appendix 1) or patient held monitoring booklet with a sticker containing this information attached.

3.4.3 Should a liquid be required, 10mg/5ml is the agreed standard strength of that must be used. Each patient must receive written information about the strength of oral methotrexate dispensed either using an information card (Appendix 1) or patient held monitoring booklet.
3.4.4 Prescriptions/orders must be clinically checked against the patient’s Kardex by a pharmacist before a dose is dispensed. To further inform the clinical check, the patient held monitoring booklet may be referred to. Any queries must be resolved either with the clinical pharmacist or directly with the prescriber.

3.4.5 Weekly doses must include the warning ‘To be taken once a week’.

3.4.6 Dispensed doses must be labelled with the patient’s name and directions.

3.4.7 Only doses labelled with the patient’s name must be administered to that patient.

3.4.8 A register of dispensed doses must be maintained in Pharmacy.

3.4.9 Dispensing of oral methotrexate for hospital wards/departments must be done only by the hospital Pharmacy and in accordance with standard operating procedures (SOPs). These SOPs must include a process for resolving clinical queries about the methotrexate prescription.

3.4.10 Counselling about handling and disposal of oral methotrexate must be given to patients.

3.5 Administration of oral methotrexate

3.5.1 Patients’ Own Supplies of methotrexate tablets must NOT be used in hospital.

3.5.2 Only doses dispensed and labelled with the patient’s name by the Trust hospital Pharmacy must be administered in hospital.

3.5.3 Medication administration and checking procedures as outlined in Use and Control of Medicines\(^4\) must be followed.

3.5.4 Methotrexate is a cytotoxic drug and must be handled according to COSHH. If necessary, methotrexate must be disposed of as per Trust policy.

3.5.5 Whenever possible, the dose to be administered should be confirmed with the patient. If appropriate, the patient should be asked to confirm that a dose is due.
3.6  **Ordering and supply**

3.6.1 For inpatient supply the patient’s Kardex should be sent to Pharmacy with the order or the clinical pharmacist asked to check the Kardex on the ward and order the dose. Single doses only will be dispensed.

3.6.2 For supply on discharge, the patient’s Kardex should be sent to Pharmacy with the discharge prescription, or the clinical pharmacist asked to check it at ward level before sending the discharge prescription to Pharmacy.

4.0  **Scope of this policy**

This policy applies to all medical, pharmacy and nursing staff that prescribe, supply, administer or monitor oral methotrexate. Patients receiving oral methotrexate could be admitted to any ward or receive outpatient treatment for co-existing conditions. Staff in all areas may therefore be involved in ensuring continuity of prescribing and monitoring or administering oral methotrexate.

5.0  **Roles and responsibilities**

5.1 All staff that prescribe, supply, administer or monitor oral methotrexate must adhere to this policy.

5.2 Managers must ensure this policy is included induction programs for medical, nursing and pharmacy staff.

5.3 The SHSCT Drugs and Therapeutics Committee is responsible for monitoring adherence to this policy and identifying if review is required earlier than otherwise indicated.

6.0  **Equality and Human Rights Considerations**

6.1 This policy has been screened for equality implications as required by Section 75 and Schedule 9 of the Northern Ireland Act 1998. Equality Commission guidance states that the purpose of screening is to identify those policies which are likely to have a significant impact on equality of opportunity so that greatest resources can be devoted to these.
6.2 Using the Equality Commission’s screening criteria, no significant equality implications have been identified. The policy will therefore not be subject to an equality impact assessment.

6.3 Similarly, this policy has been considered under the terms of the Human Rights Act 1998, and was deemed compatible with the European Convention Rights contained in the Act.

7.0 Alternative formats

This document can be made available on request in alternative formats, e.g. plain English, Braille, disc, audiocassette and in other languages to meet the needs of those who are not fluent in English.

8.0 Records Management

The supply of information under the Freedom of Information does not give the recipient or organisation that receives it the automatic right to re-use it in any way that would infringe copyright. This includes, for example, making multiple copies, publishing and issuing copies to the public. Permission to re-use the information must be obtained in advance from the Trust.

9.0 References


3. Interface Pharmacists Network for Specialist Medicines.


Appendix 1
<table>
<thead>
<tr>
<th><strong>Methotrexate tablets</strong></th>
<th><strong>Methotrexate liquid</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>There are two strengths of methotrexate tablets, 2.5mg and 10mg</td>
<td>There are various strengths of methotrexate liquid.</td>
</tr>
<tr>
<td><strong>In Northern Ireland, to reduce confusion, only methotrexate 2.5mg tablets should be used. This is the strength you have been supplied with.</strong></td>
<td><strong>You have been supplied with the 10mg/5ml strength of liquid.</strong></td>
</tr>
<tr>
<td>If you are unsure how to take your dose, please ask your doctor, nurse or pharmacist</td>
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</tr>
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</table>

Developed by Northern Ireland Medicines Governance pharmacists August 2003. Revised August 2007