

## **Policy for the safe use of oral methotrexate in secondary care**

### **Background**

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 was first developed by the Medicines Governance team in August 2003. It has now been reviewed and updated by the team and will assist Trusts' implementation of DHSSPS 'Recommendations to improve the safe use of oral methotrexate in primary and secondary care in Northern Ireland(revised) (2005)'<sup>1</sup> and NPSA Patient Safety Alert 'Improving compliance with oral methotrexate guidelines (2006)'.<sup>2</sup>

### **Aim of the policy**

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

### **Scope**

All medical, pharmacy and nursing staff within secondary care. 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.

### **Prescribing oral methotrexate**

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.
2. Baseline tests should be conducted, monitoring schedule explained, and a patient-held monitoring booklet issued as specified in the regional Shared Care Guideline for oral methotrexate<sup>3</sup>.

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.
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.
5. For in-patients when weekly oral methotrexate is prescribed and where the Kardex style allows, the prescriber must cross out the six days of the week in the administration section of the Kardex when a dose must not be administered. 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.
6. Discharge and outpatient prescriptions and discharge summary information must state the dose, frequency, formulation and day the oral methotrexate is to be taken. 'As directed' must not be used as a dosage instruction.
7. Full medication reviews, conducted where possible by pharmacists, must be undertaken on admission and discharge and at review clinic appointments.
8. All prescribing, monitoring and administration requirements should be recorded in the patient's notes.
9. 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.
10. When discharging patients newly initiated on methotrexate, prescribers should follow the agreed regional Shared Care Guideline.

### **Monitoring oral methotrexate**

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.
2. The patient's current monitoring schedule on admission should be confirmed and existing test results checked as appropriate.
3. For inpatients, the monitoring schedule for the admission should be agreed taking account of the pre-admission monitoring schedule and current clinical condition. For outpatients, the regional Shared Care Guideline for oral methotrexate should be referred to for information on monitoring.<sup>3</sup>

### **Electronic prescribing and dispensing systems**

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

### **Dispensing oral methotrexate**

1. Wards/departments other than Pharmacy must not hold routine stocks of methotrexate tablets.
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. Weekly doses must include the warning 'To be taken once a week'.
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.
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.
5. Dispensed doses must be labelled with the patient's name and directions.
6. Only doses labelled with the patient's name must be administered to that patient.
7. A register of dispensed doses must be maintained in Pharmacy.
8. Dispensing of oral methotrexate 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.
9. Counselling re handling and disposal of oral methotrexate must be given to patients.

### **Administration of oral methotrexate**

1. Patients' Own Supplies of methotrexate tablets must NOT be used in hospital.
2. Only doses dispensed and labelled with the patient's name by the Trust hospital Pharmacy must be administered.
3. Medication administration and checking procedures as outlined in Use and Control of Medicines<sup>4</sup> must be followed.
4. Methotrexate is a cytotoxic drug and must be handled according to COSHH. If necessary, methotrexate must be disposed of as per Trust policy.
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.

### **Training and education**

1. All medical, nursing, midwifery and pharmacy staff, including locum staff, must be made aware of this policy as part of their induction.

To comply with this policy, the procedure for ordering is:

### **Supply arrangements**

#### **For in-patients:**

- Send the patient's Kardex to Pharmacy with the order or ask the clinical pharmacist to check the Kardex on the ward and order the dose. Single doses only will be dispensed.

### **For discharge**

- Send the Kardex to Pharmacy with the discharge prescription, or
- Ask the clinical pharmacist to check it at ward level. Once checked, send the prescription to Pharmacy.

If you have any questions about this policy, please contact [Trust to specify ]

### **References**

1. Department of Health, Social Services and Public Safety. HSS(MD)22/2005 Recommendations to improve the safe use of oral methotrexate in primary and secondary care in Northern Ireland (revised) 2005.
2. National Patient Safety Agency 2006. Improving compliance with oral methotrexate guidelines. <http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/alerts/oral-methotrexate>
3. Interface Pharmacists Network for Specialist Medicines. <http://www.ipnsm.n-i.nhs.uk/library/ORALMETHOTREXATESCGOCT06.pdf>
4. Department of Health, Social Services and Public Safety 2004. [http://www.dhsspsni.gov.uk/use\\_control\\_of\\_medicines.pdf](http://www.dhsspsni.gov.uk/use_control_of_medicines.pdf)

### **Appendix 1**

#### **Methotrexate tablets**

There are two strengths of methotrexate tablets, 2.5mg and 10mg

In Northern Ireland, to reduce confusion, only methotrexate 2.5mg tablets should be used.

This is the strength you have been supplied with.

If you are unsure how to take your dose,  
please ask your doctor, nurse or  
pharmacist

Developed by Northern Ireland Medicines Governance pharmacists  
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## **Methotrexate liquid**

There are various strengths of methotrexate liquid.

You have been supplied with the 10mg/5ml strength of liquid.

If you are unsure how to take your dose, please ask your doctor, nurse or pharmacist.

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