

Patient safety alert

13



Alert

1 June 2006

Immediate action	<input checked="" type="checkbox"/>
Action	<input type="checkbox"/>
Update	<input checked="" type="checkbox"/>
Information request	<input type="checkbox"/>

Ref: NPSA/2006/13

Improving compliance with oral methotrexate guidelines

Oral methotrexate is a safe and effective medication if taken at the right dose and with appropriate monitoring. However, as the NPSA's patient safety alert (03)¹ highlighted, very occasionally problems with taking the medication can cause serious harm and even death.

Since July 2004 the NPSA has received 165 reports of patient safety incidents involving oral methotrexate. Of these, 14 happened before the launch of patient safety alert (03) on 29 July 2004 and the remaining 151 happened after this date. Feedback from the Safety Alert Broadcast System (SABS) indicates that 18 per cent (104 out of 569) of NHS organisations in England have still not reported having fully implemented the actions set out in patient safety alert (03).

The NPSA is issuing this subsequent alert to remind all NHS organisations of the actions they need to take to prevent such incidents occurring. Updated information for patients about oral methotrexate is also available and NHS organisations should be aware of the importance of giving this to them.

Action for the NHS

All NHS organisations (including NHS foundation trusts) should take the following steps:

- 1 Ensure all actions described in the NPSA's previous patient safety alert (03) are completed (see page 4 for details). Carry out local self-assessments to check compliance with patient safety alert (03) and with the three checklists on pages 2,3 and 4.
- 2 Give patients who are taking oral methotrexate the core patient information leaflet and monitoring document. These have been reviewed in collaboration with the British Society for Rheumatology (BSR) and the British Association of Dermatologists (BAD), both of whom support the content and their being issued to patients (see page 4 for details).

For response by:

- NHS acute trusts (including foundation trusts), mental health trusts and primary care organisations in England and Wales

For action by:

- Medical directors in England and Wales

We recommend you also inform:

- Clinical governance leads
- Clinical leads for rheumatology, gastroenterology and dermatology
- Risk managers
- Nursing directors
- Chief pharmacists/pharmaceutical advisors
- Heads of IT

- Communications leads
- Patient advice and liaison service staff in England
- Procurement managers

The NPSA has informed:

- Chief executives of acute trusts, mental health trusts and primary care organisations in England and Wales
- Chief executives/regional directors and clinical governance leads of strategic health authorities (England) and regional offices (Wales)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- The Healthcare Commission

- Healthcare Inspectorate Wales
- NHS Purchasing and Supply Agency
- Welsh Health Supplies
- Royal colleges and societies
- Methotrexate manufacturing or licence holder companies
- Prescribing and dispensing IT system suppliers
- NHS Direct
- Relevant patient organisations and community health councils in Wales
- The Independent Healthcare Forum
- Monitor
- Quality Improvement Scotland and DHSSPS Northern Ireland



Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 30 June 2006

Action plan to be agreed and actions started

**Deadline (actions from patient safety alert (03) complete):
30 September 2006**

**Deadline (audit of local actions and safe practice checklists complete):
31 January 2007**

Further information about SABS can be found at
www.info.doh.gov.uk/sar/cmopatie.nsf

Resources

The following checklists were developed to accompany patient safety alert (03) and have been reproduced here for ease of reference. These checklists should form the basis of clinical practice. The aim is to ensure that local monitoring and clinical practice are consistent across the NHS.



Safe prescribing practice checklist

Information on the risks and benefits of oral methotrexate should be given to the patient. Confirmation of the patient's understanding and consent should be sought, baseline tests conducted, monitoring schedule explained, and patient-held monitoring booklet issued.

For NHS organisations with Shared Care Guidelines, the following issues should be addressed: clarity of prescribing and monitoring responsibilities; how often blood tests will be conducted and in which location; which clinician will be responsible for receipt and review of the results; who will communicate any necessary dosage changes to the patient and the GP; and who will record test results on the patient-held monitoring booklet. Drugs and Therapeutics Committees should refer to the section on managing risk within the Department of Health's Medicines Management Framework.²

NHS organisations without Shared Care Guidelines must make similar appropriate arrangements. The BSR has published guidelines on the monitoring of disease modifying drugs, including oral methotrexate, which may be a useful source of information.

All prescribers must avoid the use of 'as directed' in prescribing – a specific dose must be applied to each prescription. Bear in mind that patients often understand their dose by the number of tablets they take rather than 'mg'. The required quantity and frequency of dose should be regularly discussed with the patient.

Repeat prescriptions should be retained separately for prescriber review prior to authorising. It may help to change the printer driver software so that it shades the prescription signature space on FP10/WP10 to alert the prescriber to this high-risk drug.

Be aware of patients who attend with symptoms such as breathlessness, dry persistent cough, vomiting or diarrhoea, as these can be signs of oral methotrexate toxicity or intolerance.

Patient safety alert 13

Improving compliance with oral methotrexate guidelines

Page 3 of 8



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. Full medication reviews,³ conducted where possible by pharmacists, should be undertaken on admission and prescribing, monitoring and administration requirements should be recorded in the patient's notes.

It is the prescriber's responsibility to record the correct dosage and frequency on the hospital drug administration chart, and to strike out the six days of the week when a dose must not be administered.

Handwritten prescriptions and discharge summary information must be complete, legible and include the form, strength, dose and directions in full.



Safe dispensing practice checklist

Ask to see the patient's monitoring booklet and check if any dose changes have been made since the last prescription issue.

Assess the needs of the individual patient. For example, if the new packaging is not available, patients who have reduced manual dexterity should be given larger containers or ribbed easy-to-grip lids as this could reduce the likelihood of them decanting the tablets into another container at home (Disability Discrimination Act applies).

The strength of tablet supplied to the patient must stay consistent to prevent any confusion about the number of tablets they need to take, and the patient's monitoring document and Patient Medication Record should be checked to confirm the previous supply.

Tell the patient their dose in terms of quantity of tablets and weekly frequency. Give the patient a monitoring booklet if they have not already got one.

Show the patient how to differentiate between the oral methotrexate and folic acid packaging. If they take both medicines at the same time, they will need to know how to distinguish between them, given that both may be round yellow tablets of similar size.

Be aware of patients who attend with symptoms such as breathlessness, dry persistent cough, vomiting or diarrhoea, as these can be signs of oral methotrexate toxicity or intolerance. You may need to refer them back to the prescriber. It is good practice to maintain a record of any over-the-counter items supplied to the patient.



Safe administration practice checklist

Check the patient's wristband against the medication administration record and the pharmacy labels attached to the medicine's container. Check the patient's name, the medicine, the strength of tablet, the dose and the timing.

Ask the patient to confirm that the medicine is required. This includes checking whether any new medications have been started since the last dose of methotrexate was administered.

Record the medication given on to the medication administration record at the time of administering it; a delay in recording it can result in one or more additional doses being given.

Update on the action points in patient safety alert (03)

Patient safety alert (03) requested that NHS organisations take four specific actions. These are listed below, with details of any updates.

1 Agree local action required

Agree appropriate local risk reduction actions through your Drugs/Medicines and Therapeutic Committee. Self-assessments of compliance will provide the relevant information that trusts in England and Wales will be required to provide to the Healthcare Commission and Healthcare Inspectorate Wales (HIW) respectively as evidence of implementation of NPSA solutions.

2 Provide patient information before and during treatment

The NPSA provided recommended core content for a pre-treatment information leaflet and a patient-held monitoring and dosage record during treatment.

Update

Revised patient information materials have been developed in collaboration with the British Society for Rheumatology (BSR) and the British Association of Dermatologists (BAD). An information leaflet that should be used as part of an educational programme for the patient and to support clinical teams is now available; it is not intended to be a substitute for discussing treatment with the patient. There is also a monitoring booklet that will provide a generic source of up-to-date information for all staff caring for patients taking oral methotrexate.

These documents are available to download from the NPSA website at www.npsa.nhs.uk/health/alerts

Local information can be added to either or both of these documents, for example, single strength prescribing policies, or other locally agreed evidence-based information.

Alternatively, trusts may wish to collaborate and order printed copies of a combined single version of the information leaflet and monitoring document. Enquiries for bulk orders should be referred to NHS Non-secure Forms c/o Cheshire Health Agency.

Organisations in Wales may order printed copies of these documents by calling Communis on 02920 365900.



3 Update prescribing and dispensing software programmes

All prescribing and dispensing software programmes in primary and secondary care locations must be updated with the latest software which includes oral methotrexate alerts and prompts.

Update

In evaluating patient safety alert (03), the NPSA conducted two surveys (January 2005 and July 2005) of the extent to which the IT specification has been implemented by system providers. It found that very few companies had incorporated all of the safety features included within the IT specification. In fact, some companies had specifically chosen to only implement some of the features, thereby providing a system with increased risk rather than increased safety.

The NPSA has provided this information to NHS Connecting for Health for inclusion in their future specification for patient safety. The NPSA has also updated the specification to take account of the growing trend toward single strength prescribing, and has re-circulated the specification to all system suppliers, urging an immediate update.

NHS organisations should make sure that any new prescribing and dispensing software programmes incorporate the updated specification.

The updated specification is available on the NPSA website at www.npsa.nhs.uk/health/alerts

4 Review purchasing

Purchasers of 2.5mg and 10mg oral methotrexate tablets should ensure that the tablets are visually distinguishable by shape, and that packaging contains the cautionary wording required by the Medicines and Healthcare products Regulatory Agency (MHRA).

Update

Developments with the pharmaceutical industry continue to progress. Clinical trials of new packaging with improved design (for patients with reduced manual dexterity), labelling and safety information are taking place in specialist rheumatology locations. The new packaging will contain reduced quantities of tablets, equivalent to one, two or three month's treatment, depending upon individual dose. This will also reduce the need for handling during dispensing.

The new packaging should be given to patients as soon as possible following the new packs reaching the market. There will be a period during which both the current pack sizes (28 and 100 tablets) and the new pack sizes (16 and 24 tablets) will be available. To prevent confusion, the changed packaging should be clearly explained to patients when they receive their packs. Pharmacy or dispensary staff should risk assess the storage and supply of the packs during the period of changeover to prevent selection or dispensing errors.

Findings from the National Reporting and Learning System

Of the 165 reports of incidents directly associated with oral methotrexate that the NPSA has received since July 2004:

- 139 (84 per cent) occurred in general or acute hospital settings and 26 (16 per cent) occurred in primary care settings*;
- 140 caused no harm to the patients involved, 13 caused low harm, eight caused moderate harm, two caused severe harm and two led to the patients' deaths;

* This proportion may reflect the overall reporting rates from these settings as opposed to the proportion of actual incidents occurring.

Patient safety alert 13

Improving compliance with oral methotrexate guidelines Page 6 of 8



- 40 per cent were related to incorrect prescribing of oral methotrexate (58 incidents from secondary care and nine from primary care) – the most common incident type. 21 of these prescribing incidents were described as ‘near misses’ whereby the mistake was intercepted by the pharmacist and corrected before the patient received their medicine.
- 25 per cent were associated with those stages of care outlined in the safe practice checklists provided in patient safety alert (03). These checklists are replicated in this alert (pages 2, 3 and 4) to highlight the critical stages where risk can be reduced.

Of these 165 incidents, 151 occurred since patient safety alert (03) was issued. The actions described in the alert were specifically intended to:

- prevent prescribing and dispensing incidents;
- prevent patients from taking an incorrect dose or failing to attend for scheduled blood tests;
- prevent or reduce communication breakdowns by making information on oral methotrexate available to patients;
- help share blood test results to enable action to be taken in response to signs of toxicity.

The Chief Medical Officer’s (England) Annual Report 2004⁴ highlighted the NPSA’s patient safety alert (03) on oral methotrexate as an example of a patient safety alert that NHS organisations appear from their reports to have been slow to comply with. NHS organisations were given 245 days from the date it was issued to complete the actions. Twenty per cent had done so within the first 80 days. However, by the deadline date, only 45 per cent of NHS organisations had completed the actions.

In addition to these incidents, the NPSA has received a further five reports of patient deaths attributed to the administration of oral methotrexate. However, from the information the NPSA received about the incidents, it has not yet been possible to conclude the exact cause of death or the role, if any, oral methotrexate had in contributing to these deaths.

Based on the number of patient safety incident reports related to oral methotrexate the NPSA has received, some assumptions about the potential causes for error and the proportion of incidents that could have been prevented have been made:

- better compliance with the NPSA patient safety alert (03) might have prevented 37 per cent of incidents;
- implementation of risk assessment IT specifications in hospital electronic prescribing systems might have prevented 75 per cent of incidents;
- individual staff practising safer prescribing, dispensing and administration of oral methotrexate might have prevented 25 per cent of incidents. In these cases it was found that:
 - twelve per cent were due to incorrect or inappropriate medicine administration to the patient;
 - ten per cent were due to inaccurate information recorded in the patients’ notes;
 - three per cent were due to omissions of treatment.



Background

During a ten year period (1993–2002), the NPSA is aware of 137 patient safety incidents associated with the use of oral methotrexate. These incidents were reported to litigation agencies or described in peer-reviewed literature in England. Of these, 25 resulted in patients' deaths and a further 26 resulted in serious harm to patients.

Two-thirds (67 per cent) of these incidents involved prescribing the wrong frequency of dose, 19 per cent were due to a lack of, or poor monitoring of, therapy and seven per cent were because of misidentification of the tablets by professionals or patients.

Contacts

For further details about the NPSA's work on oral methotrexate, please contact:

Wendy Harris
Head of Safety Solutions
National Patient Safety Agency
4-6 Maple Street
London
W1T 5HD

Tel: 020 7927 9500

Email: wendy.harris@npsa.nhs.uk

References

- 1 *Reducing the harm caused by oral methotrexate*, National Patient Safety Agency, 29 July 2004.
- 2 *Medicines Management in NHS Trusts: hospital medicines management framework*, Department of Health, September 2003. Gateway ref: 1785
- 3 *Room for Review*, Medicines Partnership, 2002, www.medicines-partnership.org/medication-review
- 4 'Learning how to learn: compliance with patient safety alerts in the NHS', *Annual Report of the Chief Medical Officer 2004*, 19 July 2005 .

Patient safety alert 13

Improving compliance with oral methotrexate guidelines
Page 8 of 8



A patient safety alert requires prompt action to address high risk safety problems.

This patient safety alert is written in the following context:

It represents the view of the National Patient Safety Agency, which was arrived at after consideration of the evidence available. It is anticipated that healthcare staff will take it into account when designing services and delivering patient care. This does not, however, override the individual responsibility of healthcare staff to make decisions appropriate to local circumstances and the needs of patients and to take appropriate professional advice where necessary.

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