

New patient safety solutions to prevent deaths linked to Methotrexate

The National Patient Safety Agency (NPSA) recently announced a package of practical solutions to reduce errors associated with the use of the drug oral Methotrexate. The NPSA has joined forces with the three pharmaceutical companies that manufacture the drug in the UK in a unique collaboration to improve patient safety.

Oral Methotrexate is taken in tablet form by thousands of people in the UK, normally for the treatment of moderate to severe rheumatoid arthritis and severe psoriasis. It is a safe and effective medication if taken at the right frequency and in the right dose, and with appropriate monitoring. However, the NPSA has identified 25 patient deaths and 26 cases of serious harm linked to the use of oral Methotrexate in a community setting over a 10 year period in England. The NPSA has also established that the problem is well-documented in the US and Australia.

Detailed analysis by the NPSA has identified key underlying factors including: patients not sufficiently informed about how the drug should be taken, for example on a weekly, and not a daily basis; health professionals and patients not benefiting from clear packaging or eye-catching messages on packaging across the industry; and variations in patient monitoring and treatment reviews.

In its first full year of operation (2002/3), the NPSA has collaborated with health professionals, patient groups, the pharmaceutical industry and medical and

pharmaceutical software suppliers, to identify and develop three national solutions:

1. A new patient treatment diary, trialled with patients and patient groups, to empower patients with information, enable them to keep their own track record, and to ensure they are monitored correctly.

2. Pfizer, Goldshield and Mayne Pharma, the three UK manufacturers of Methotrexate, are working with NPSA and MHRA to develop new packaging designs and build on patient information currently available as part of a longer term piece of work that will help to improve safety when Methotrexate is prescribed by healthcare staff and administered by patients and their carers.

3. A project to adapt IT systems in GP surgeries and community pharmacies to incorporate flagging mechanisms and default settings to support NHS staff by designing out opportunities for human error in prescribing the drug.

Each solution will be developed in collaboration with the major stakeholders, and subject to further testing and risk assessment by the NPSA.

Wendy Harris, Senior Pharmacist at the NPSA, said: "Whilst the vast majority of people who take Methotrexate receive safe and effective treatment, there are some key patient safety issues we have to tackle. Methotrexate is a powerful drug, and one of only five drugs in the country taken at a weekly dose*. This

leads to mistakes, both by patients and healthcare professionals.

"As this is a complex problem, we are working on a range of solutions and consulting with all the parties involved. We are delighted that three pharmaceutical companies have decided to work with us in a shared effort to tackle this issue across the industry. There is great potential to reduce the errors associated with this drug, and to translate much of the learning both internationally and to future NPSA projects focused on reducing medication errors in the NHS."

* There are 13,000 medicines currently licensed for use in the UK. Oral Methotrexate is one of only five medicines that should be taken on a weekly basis. Note: Oral Methotrexate is taken on a more frequent basis for specific conditions, for example by cancer patients who may be prescribed the drug on a daily basis as part of their hospital care.

During 2002 the Committee on Safety of Medicines (CSM) made a recommendation on how the labelling of manufacturer's packs of Methotrexate tablets could be improved to assist in reducing the potential for error. This change has already been progressed by the Medicines and Healthcare products Regulatory Agency (MHRA) which is responsible for acting on behalf of ministers in relation to the licensing of all medicines. New labelling statements will begin to appear in pharmacies.