Rheumatology

Methotrexate 2.5mg Tablets

Produced by The 3T's Formulary

Further copies can be obtained from:
Pharmacy Department, Great Western Hospital
NHS Wiltshire

Addressograph label

Patient's Name _____

Consultant Name _____

Consultant Signature _____

Date _____

I agree to your request to prescribe Methotrexate in accordance with the attached shared care guideline:

GP Name _____

GP Signature _____

Date _____

Methotrexate 2.5mg Tablets (TLS Amber)

For use in Rheumatoid arthritis, psoriatic arthritis, and other forms of inflammatory arthritis

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines how responsibility for prescribing methotrexate tablets might be shared between specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes this medication legally assumes clinical responsibility for methotrexate tablets and the consequences of its use.

RESPONSIBILITIES and ROLES

	Specialist responsibilities
1	Perform initial assessment of patient prior to initiation of methotrexate, including baseline monitoring of renal function, liver function and full blood count (FBC), and a baseline chest X-Ray if the patient has not had a previous normal chest X-Ray in the last 12 months.
2	Ensure that female patients are not pregnant. Explain to both male and female patients the importance of not conceiving during and for six months after treatment with methotrexate.
3	Initiate treatment and prescribe at least the first month supply of medication.
4	Issue patient with a methotrexate monitoring booklet and explain that only 2.5mg tablets will be issued.
5	Discuss the benefits and side effects of treatment with the patient and emphasise the importance of regular monitoring and the importance of reporting any signs or symptoms of infection promptly.
6	Ask the GP whether he or she is willing to participate in shared care, and discuss the shared care arrangement with the patient & obtain their consent.
7	Ensure compatibility of methotrexate with other concomitant medication.
8	Supply GP with summary within 14 days of a hospital out-patient review or in-patient stay.
9	Review the patient's condition and monitor response to treatment at least annually or as deemed clinically necessary.
10	Give advice to the GP concerning ongoing prescribing, monitoring, dosage adjustments and when to stop treatment.
11	Report adverse events to the MHRA & GP.
12	Ensure clear backup arrangements exist for GPs to obtain additional advice and support should they need it.

	General Practitioner responsibilities
1	Reply to the request for shared care as soon as practicable.
2	Prescribe medicine at the dose and frequency recommended by the specialist.
3	Undertake monitoring as per monitoring schedule on page 4.
4	Ensure compatibility of methotrexate with other concomitant medication.
5	Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
6	Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
7	Stop treatment on the advice of the specialist.
8	Report adverse events to the specialist and MHRA.

	Patient's role
1	Attend all appointments with GP and specialist. Including appointments for blood tests and other monitoring.
2	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
3	Report any signs or symptoms of infection to the specialist or GP promptly.
4	Share any concerns in relation to treatment with medicine.
5	Inform specialist or GP of any other medication being taken, including over-the-counter products.
6	Report any adverse effects to the specialist or GP whilst taking the medicine.
7	Patients should keep alcohol consumption within well defined limits (do not exceed 21 units per week for men and 14 units per week for women and have at least one alcohol free day each week)

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Email address:
Specialist (Rheumatology):			
Dr E Price – Consultant Rheumatologist	01793 604314	2112	Elizabeth.Price@gwh.nhs.uk
Dr L Williamson – Consultant Rheumatologist	01793 604318	1263	Lyn.Williamson@gwh.nhs.uk
Dr D Collins – Consultant Rheumatologist	01793 604317		David.Collins@gwh.nhs.uk
GWH Medicines Information	01793 605029		medinfo@gwh.nhs.uk
Rheumatology Team – Osprey Department	01793 604323		

SUPPORTING INFORMATION

Indications:
Rheumatology

- Disease modifying therapy in Rheumatoid arthritis, psoriatic arthritis (unlicensed indication) and other forms of inflammatory arthritis including juvenile arthritis (unlicensed indication).

Dosage and administration – refer to SPC for further information on dosing

METHOTREXATE MUST ONLY BE ADMINISTERED **ONCE A WEEK**

- Starting dose 10-15mg once a week (off-label starting dose), escalated to achieve an optimal response. Many patients will respond to 20mg/week (licensed maximum dose), but some may require 25-30mg/week (off-label maximum dose, in line with British Society of Rheumatology guidance, National Rheumatoid Arthritis Society guidance and professional best practice).

- All doses should be prescribed as 2.5mg tablets to be taken as a single dose once a week on the same day each week.

- An oral folic acid supplement should also be prescribed either as 5mg or 10mg ONCE a WEEK, taken on a different day of the week to methotrexate, or as 5mg daily except on the day methotrexate is taken. The latter is usually only necessary if mouth ulcers are a particular problem.

Contra-indications and precautions for use – see SPC for full list of contraindications and precautions

- Contra-indicated in hypersensitivity to methotrexate or any of the excipients
- Contra-indicated in severe/significant renal or significant hepatic impairment
- Contra-indicated in patients with pre-existing blood dyscrasias (e.g. significant marrow hyperplasia, leucopenia, thrombocytopenia or anaemia)
- Methotrexate is teratogenic and should not be given in pregnancy or to breastfeeding mothers
- Both **male** and **female** patients should use effective contraception **during** and **for at least 3 months** (but ideally 6 months) **after** treatment.
- Use more caution in the elderly.

- Influenza vaccination and pneumovax are recommended for patients during treatment with methotrexate

Side-effects

- Most commonly: nausea, mouth ulcers, GI upset
- Other side effects include: hepatotoxicity, lung disease or bone marrow suppression
- Patients should be advised to report all signs and symptoms of infection, especially sore throat, due to the potential for haematopoietic suppression
- Patients should be advised to contact their specialist if they develop a cough or dyspnoea

Refer patient back to the specialist if any of these side-effects cause concern. **Refer to the SPC for a full list of adverse effects** & further information http://www.medicines.org.uk.

This medicine does not have black triangle (▼) status. Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the MHRA.

Monitoring

Parameter	Frequency of monitoring	Action (adjustment and referral back to hospital)
Liver Function	Monthly for 6 months then 3 monthly once stable	If ALP, ALT and/or AST rise to more than 3 times the upper limit of normal, contact the specialist urgently for advice.
Renal Function		If there is a new fall or persistent downward trend in GFR, seek advice from specialist on dose reduction.
Full Blood Count (incl.platelets)		If WBC <4.0, neutrophils <2.0, lymphocytes <0.5 or platelets <150, contact the specialist urgently for advice.
New or increasing dyspnoea	Adhoc	If symptoms develop, withhold treatment and discuss with specialist
New or increasing skin rash/ ulceration		

It is important to note that a low lymphocyte count is usually a marker of disease activity, and so the dose of methotrexate would not generally be reduced if the patient's lymphocyte count is low.

Methotrexate tends to suppress neutrophil count and occasionally platelet count (although this can also be a marker of disease activity). Of greatest importance is the change from baseline and rate of fall, and the specialist may choose not to reduce the dose of methotrexate if the patient's WBC, neutrophils and/or platelets are below the levels stated above but are stable.

If the specialist advises a change in the dose of methotrexate within the first 6 months of treatment, FBCs will generally just be rechecked as part of the next monthly blood test. However, if the dose of methotrexate is changed more than 6 months after initiation of treatment, the specialist will advise when to recheck FBCs.

Drug Interactions – see SPC for full details of drug interactions

- Avoid concomitant administration of trimethoprim, co-trimoxazole and nitrous oxide.
- Immunological response to concurrent vaccination may be decreased. Avoid live vaccines.
- The concurrent administration of agents such as p-aminobenzoic acid, chloramphenicol, phenytoin, anti-inflammatory agents, tetracyclines, thiazide diuretics, probenicid or sulfinpyrazone or oral hypoglycaemics will decrease the methotrexate transport function of renal tubules, thereby reducing excretion and almost certainly increasing methotrexate toxicity.
- NSAID's may increase blood levels of methotrexate, care should be taken when initiating treatment and monthly monitoring is essential. If stabilised on both (or if NSAID is given short term) then treatment with methotrexate should **not** be stopped. Low dose aspirin antiplatelet treatment (75mg orally once daily) may be given safely with methotrexate.
- Hepatic and nephrotoxic drugs should be avoided
- Acitretin should be avoided (See SPC).

Cost

Methotrexate 2.5mg Tablets x 28 - £4.61

(NHS Drug Tariff - January 2013)

References

- Electronic Medicines Compendium. Summary of Product Characteristics. Matrex Tablets 2.5mg (Methotrexate)

http://www.medicines.org.uk/EMC/medicine/6003/SPC/Maxtrex+Tablets+2.5+mg/

- Electronic Medicines Compendium. Summary of Product Characteristics. Methotrexate 2.5mg Tablets (Hospira)

http://www.medicines.org.uk/EMC/medicine/12033/SPC/Methotrexate+2.5+mg+Tablets/

Author: Katherine Roe, Formulary Pharmacy Technician, GWH

Date written: May 2013

Date of review: December 2015