Royal Berkshire NHS
NHS Foundation Trust

PRESCRIBING GUIDANCE
METHOTREXATE for the treatment of vasculitis

For the latest information on interactions and adverse effects, always consult the latest version of the Summary of Product Characteristics (SPC), which can be found at: http://www.medicines.org.uk/

Approval and Authorisation

Approved by	Job Title	NAME	Date
Renal CG	Chair	Dr B Alchi	18/07/2016
RBFT DTC	Chair	S Hussain	10/11/2017
GP MOC	Chair	Dr W Beacham	21/06/2017

Change History

Version	Date	Author	Reason

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Introduction

This guidance has been prepared to support healthcare professionals in the implementation of shared care management of patients who have been prescribed methotrexate for the treatment of vasculitis.

Methotrexate is a folic acid antagonist and is classified as an antimetabolic cytotoxic immunosuppressant agent.

Dose

The usual dose of methotrexate is up to 25mg once a week.

Clinical response to treatment can usually be expected in 6-12 weeks.

Folic Acid

The patient must be prescribed folic acid to be taken orally the day after their methotrexate. Clinical trials have shown that supplementation with folic acid reduces the gastro-intestinal side effects of methotrexate by up to 80%. Folic acid must not be taken on the day of treatment as efficacy of the treatment will be impaired. The recommended dose of folic acid should be the same as the methotrexate dose.

Cautions

- Patients should try to avoid contact with people who have active chickenpox or shingles and should report any such contact to their GP or hospital specialist.
- Due to diminished hepatic and renal function and decreased folate stores, methotrexate should be used with extreme caution in elderly patients, a reduction in dosage should be considered and these patients should be closely monitored for early signs of toxicity.
- Obese patients may have prolonged excretion of methotrexate

Contraindications

- Known sensitivity
- Significantly impaired hepatic function (LFT's x2 of normal values)
- Significantly impaired renal function (avoid if GFR < 30ml/min)
- Pre-existing blood dyscrasias, such as bone marrow hypoplasia, significant anaemia, leucopenia, or thrombocytopenia
- Alcoholism
- Severe acute or chronic infections and immunodeficiency syndrome
- Pregnancy and breast-feeding
- Pleural effusion/pleural fibrosis.

Side effects

- Gastro-intestinal disturbances - Nausea, vomiting, diarrhoea, anorexia and abdominal discomfort
- Hepatotoxicity (hepatic necrosis, biliary stasis)
- Bone marrow suppression (leucopoenia, thrombocytopenia) and therefore increased risk of infection
- Oral ulceration, rarely gastrointestinal ulceration
- Hypersensitivity reactions (fever, rigors, rash, myalgia, arthralgia, hypotension, dizziness)
- Rarely pancreatitis, interstitial nephritis
- Alopecia

At the beginning of treatment the patient should be advised to report any signs of bone marrow suppression (i.e. infection, fever, unexplained bruising or bleeding) to the GP and Consultant.

Interactions

- Precautions should be taken with concurrent administration of methotrexate and:
- Aspirin, NSAIDS, diuretics, hypoglycaemics, tetracycline, chloramphenicol, phenytoin, probenicid, penicillin.
- Trimethoprim and co-trimoxazole increase the risks of toxicity
- Ciclosporin increases the toxicity of both the methotrexate and ciclosporin
- Patients should avoid ‘live’ vaccines such as oral polio, oral typhoid, MMR, BCG, chicken pox/shingles and yellow fever, whilst on immunosuppressive therapy. Contact hospital specialist for advice on any vaccinations if required.

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Criteria for Use

RESPONSIBILITIES and ROLES

Specialist responsibilities
1 Initiate treatment and prescribe until the GP formally agrees to share care (a supply of two weeks or original pack as per agreement).
2 Carry out baseline and subsequent monitoring.
3 Send a letter to the GP requesting shared care for the patient.
4 Routine clinic follow-up on a regular basis.
5 Send a letter to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated.
6 Evaluation of any reported adverse effects by GP or patient.
7 Contact GP if results of blood monitoring are abnormal with advice for e.g. suspend treatment, decrease dose etc.
8 Advise GP on review, duration or discontinuation of treatment where necessary.
9 Inform GP of patients who do not attend clinic appointments.
10 Ensure that backup advice is available at all times

Monitoring requirements and actions (to be undertaken by the hospital)
• Pre-treatment FBC, renal profile, LFTs and chest X-ray. Consider lung function tests.
• Subsequent Monitoring ▪ **FBC, renal profile and LFTs** – fortnightly after each dose change for 6 weeks. Thereafter monthly for 1 year, and then every 3 months if treatment continues.

General Practitioner responsibilities
1 Monitor patient's overall health and well being.
2 Prescribe the drug treatment as described
3 Report any adverse events to the hospital specialist, where appropriate
4 Help in monitoring the progression of disease.
5 Alert the hospital of any suspected non-compliance with treatment.

Patient's / Carer's role
1 Ask the specialist for information, if he or she does not have a clear understanding of the treatment.
2 Tell the specialist of any other medication being taken, including over-the-counter products.
3 Read the patient information leaflet included with your medication and report any side effects or concerns you have to the specialist or GP

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BACK-UP ADVICE AND SUPPORT

Contact details	Specialist	Telephone No.	Email address:
Consultant nephrologists	Dr Bassam Alchi Dr Lindsey Barker Dr Nitin Bhandary Dr Cian Chan Dr Oliver Flossmann Dr Mobin Mohteshamzadeh Dr Emma Vaux	(0118) 322 1889	