PAEDIATRIC Shared Care Policy and Prescribing Information for General Practitioners for METHOTREXATE injection (Gastroenterology and Rheumatology)

Publish public	Applies to: NHS Grampian	Version 1	NHS Grampian
Coordinator:	Authorised for issue by	Document no: NHSG/SCPp/MtxInj/MGPG813	
Clinical Pharmacist	Medicines Guidelines and Policies Group	Effective date: July 2016 TBC	
Signature: J Mosley	Signature: C Hind	Review Date: July 2018	
		Supersedes: N/A – New	

Please keep this document in the patients notes

PATIENT NAME UNIT NUMBER: CHI NUMBER: ADDRESS: DATE OF BIRTH: Insert patient sticker here	HOSPITAL: WARD: TELEPHONE NO: CONSULTANT: DATE: print name) SIGNATURE:

THERAPEUTIC INDICATION FOR THIS PATIENT: (to be completed by consultant)

DOSAGE/PREPARATION/ROUTE/FREQUENCY OF ADMINISTRATION: (to be completed by consultant)

Concurrent Folic Acid **Yes / No*** Dose = 5mg (oral) **ONCE WEEKLY** 72 hours after methotrexate

SAFE PRACTICE IS THAT THE CLINICIAN WHO ORDERS THE TEST MUST ACT ON THE RESULT

CARE WHICH IS THE RESPONSIBILITY OF THE PAEDIATRIC HOSPITAL CONSULTANT

1. Baseline:
Full blood count (FBC); urea, creatinine and electrolytes (U&E); liver function tests (LFTs);CRP.

2. Copy of results to be sent to GP.

3. Exclude pregnancy before starting therapy. Advise men and women;
- To avoid conception during treatment and for at least **4 months** after discontinuation.
- Of the potential adverse effect of methotrexate on reproduction.

4. Initiation of therapy and recommendations for dose increments.

5. Decision on final dose required for patient.

6. Ensuring that patients/carers are trained to self administer the injection or ensuring that the injection can be administered by an appropriately trained healthcare professional.

7. Ensuring the process for the disposal of waste is clearly described and understood.

8. Monitoring clinical response to treatment.

9. Advise patient/parent/carer to immediately report any signs or symptoms of blood, liver or respiratory toxicity - especially sore throat, bruising, cough and dyspnoea.

CARE WHICH IS THE RESPONSIBILITY OF THE GENERAL PRACTITIONER (GP)

1. Prescribing medication under guidance of a consultant.
2. Check before prescribing that the monitoring is up to date and that results are within the normal range.
3. The GP should be aware that the drug can cause blood dyscrasias, pulmonary toxicity (rare in children), renal or hepatic damage, suppression of ovarian and testicular function.
4. Patients should be asked about signs of infection, e.g. worsening, unexplained sore throat, cough and dyspnoea or the presence of rash or oral ulceration at each visit.
When the patient has an intercurrent illness (other than a minor viral URTI in a child) a FBC, U&E, LFTs and CRP should be done. Any abnormal results including those noted above should be reported to the consultant.
5. The General Practitioner has primary responsibility for monitoring therapy according to the schedule as directed by a paediatric consultant:
- FBC, U&E, LFTs, Amylase and CRP :
  Every .....weeks for .....month(s) then every.....month(s).
- If disease and dose unstable monitoring frequency may be changed after discussion with specialist team.

6. **Prescribe folic acid 5mg once weekly if required, as above.**

When writing laboratory request forms always include details of the patient's medication

NOTE: In addition to absolute values for haematological indices a rapid fall **or a consistent downward trend in any value should prompt caution and extra vigilance.**

If something unexpected occurs Contact Consultant or specialist nurse.

Notify the consultant if the drug is withheld.

Action To Be Taken In The Event Of Abnormal Monitoring Results WITHHOLD UNTIL DISCUSSED WITH CONSULTANT / SPECIALIST NURSE	
• **Lymphocytes**	<0.5 x 10^9/L
• **Neutrophils**	<1.0 x 10^9/L
• **Platelets**	<130 x 10^9/L
• **LFTs**	**>3-fold rise in ALT** (from upper limit of reference range)
• Mild to moderate renal impairment	Increase in creatinine of 30% above baseline
• **MCV** >105fL	Investigate and if B12 or folate low start appropriate supplementation
• Rash, oral ulceration	Withhold until discussed with consultant/specialist nurse
• Unexplained fall in albumin	Withhold until discussed with consultant/specialist nurse
• Significantly unwell with new or increasing dyspnoea or cough	Withhold until discussed with consultant/specialist nurse
• Abnormal bruising or sore throat	Withhold until FBC result available. Discuss with consultant/specialist nurse

For specific product information please consult the current summary of product characteristics (http://www.medicines.org.uk/emc/ and the BNF/BNF for Children (https://www.medicinescomplete.com/mc/)

Other information

- Live vaccines should be avoided in patients taking methotrexate.
- Single pneumococcal vaccination and annual influenza vaccine should be given.
- **There are a number of drug interactions that must be considered. When a new drug is prescribed please refer to Summary of Product Characteristics, BNF or contact Medicines Information**.
  Some important interactions to consider include the following:
  - NSAIDs and aspirin can reduce excretion of methotrexate. However **standard doses of NSAIDs may be continued.** Avoid aspirin use in children. Monitoring is essential if new prescriptions added.
  - **Co-trimoxazole** or **trimethoprim** must not be co-administered with methotrexate as there is increased risk of haematological toxicity. Cases of severe bone marrow suppression have been reported. May exceptionally be prescribed on the recommendation of a paediatric consultant for prophylaxis of PJP.
  - Acitretin may increase plasma concentration of methotrexate. Caution is advised.
  - Probenicid will decrease the methotrexate transport function of renal tubules, thereby reducing excretion and almost certainly increasing methotrexate toxicity. Monitoring essential.
- Advise men or women to avoid conception during and for at least four months after discontinuation of methotrexate.

NOTE: Methotrexate injection is a cytotoxic preparation, although the ctyotoxic risk relating to the low dosages used in inflammatory conditions is believed to be minimal. Handling and disposal of syringes, including used/part used syringes should be according to local and national requirements for safe handling of cytotoxic drugs.
It is essential that methotrexate injection, including used/part-used syringes, are deposited in Yellow Stream bin container with a **violet lid, initially supplied by the hospital** and disposed of via the chemotherapy waste route. Storage and uplift must be kept separate from **all** other wastes. Full cytotoxic waste containers will be the returned to the community pharmacy or hospital clinic whichever is convenient for the patient and a replacement container issued.

Methotrexate injection is initiated by hospital consultants. The majority of patients/carers are able to administer the injection with training provided by specialist nurses. In exceptional cases administration may be arranged with community nursing teams.
Pregnant health care personnel should not handle and/or administer methotrexate injection.
Methotrexate must not come into contact with the skin or mucosa. In the event of contamination, the affected area must be rinsed immediately with ample amount of water.

Pregnancy

Discuss with consultant. Contra-indicated in pregnancy. Advise to contact physician immediately if pregnancy occur.
Breast feeding. Discuss with Aberdeen Maternity Hospital. Discontinue breast-feeding.

Responsibilities of GPs undertaking monitoring

A GP agreeing to monitor methotrexate injection should:

- Ensure that the relevant monitoring requirements are undertaken at the correct frequency.
- Ensure that the test results are checked for any abnormality as soon as the results are available.
- Ensure abnormal results are acted upon.
- Contact the consultant in the event of a drug reaction or monitoring abnormality or anything you are unhappy about.
- Be alert for any of the known adverse reactions.
- Ensure the patient's records clearly indicate the patient is receiving methotrexate injection.

**** The patient should be encouraged to ensure blood tests are taken at the correct intervals. ****