NHS Shropshire Clinical Commissioning Group

The Robert Jones and Agnes Hunt NHS Orthopaedic Hospital NHS Foundation Trust

Sodium aurothiomalate (Gold therapy)

Rheumatology Local Safety Monitoring Schedule

This local safety monitoring schedule supports clinicians under the Local Enhanced Service for High Risk Drug Monitoring (formerly Near Patient Testing). Aligning clinical and prescribing responsibility enhances patient safety because the individual signing the prescription will also be responsible for ensuring that any necessary monitoring has been undertaken and will have access to the results of this.

The prescriber and specialist assume joint clinical responsibility for the drug and the consequences of its use.

Specialist details	GP details	Patient details
Name:	Name:	Name:
Address:	Address:	Contact number:
Email:	Email:	
Contact number:	Contact number:	

Introduction

The mechanism of action of sodium aurothiomalate is not known. Benefit should not be expected until a cumulative dose of at least 500mg has been given. If there is no response after a cumulative dose of 1000mg has been given, alternative DMARD therapy should be considered.

Licensed indication: active progressive rheumatoid arthritis, progressive juvenile chronic arthritis

Adult dosage and administration

Sodium aurothiomalate should be administered **only** by deep intramuscular (IM) injection followed by gentle massage of the area.
A typical dose regimen may be: 10mg *test dose* (administered in secondary care) followed by 50mg weekly until there is a significant response or a total dose of 1000mg has been given.
In patients who respond, the interval between doses may be increased by stages from 50mg per week to 50mg every 4 weeks.
Available as: Sodium aurothiomalate injection 10mg/0.5ml, 50mg/0.5ml

It may take up to 3 months for significant response to be achieved.

Specialist responsibilities

- Provide GP with clear written advice on required dosage and frequency of Sodium aurothiomalate, written monitoring guidelines and drug information.
- Check for interactions with other medicines.
- Provide the patient/carer with relevant (written) information on use, side-effects and need for monitoring of infection.
- **Advise on need for adequate contraception.**
- Arrange pre-treatment baseline investigations either in secondary or primary care.
  Baseline tests
    - **FBC**
    - **LFTs**
    - **ESR or CRP**
    - **Urinary dipstick for protein**
    - **U&E and creatinine**

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Date prepared: March 2015 Date for review: March 2018

- An annual chest X-ray is recommended to monitor for pulmonary fibrosis, and further investigation if clinically suspected
- Review results of safety monitoring and request additional tests as required
- Administer a 10mg test dose and observe the patient for 30 minutes for signs of allergic reaction.
- Identify and report adverse events to the GP and the MHRA (via yellow card).
- Monitor disease response to treatment and need to continue therapy
- Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed
- Provide any other advice or information for the GP if required.
- Identify and report adverse events to the GP and the MHRA (via yellow card).

Primary Care responsibilities

- Prescribe and administer sodium aurothiomalate at the dose recommended if patient is having appropriate regular blood monitoring and monitoring results are within acceptable range.
- Arrange and record ongoing monitoring as agreed with specialist
    - FBC at the time of each injection. (Results of FBC need not be available before each injection is given, but must be available before the next injection)
    - ESR or CRP may be required every 3 months
    - Urinalysis must be carried out immediately before each injection

- Patients on combination DMARD therapy may need more frequent monitoring. Please check the Local Safety Monitoring Schedule for each drug.
- If patient develops symptoms/signs of systemic infection, this should be treated promptly and sodium aurothiomalate withheld until the infection has cleared.
- Report any adverse drug reactions to the initiating specialist and the usual bodies (e.g. MHRA).
- Ensure no drug interactions with other medicines
- Ask about oral ulceration/sore throat; unexplained rash or unusual bruising at every consultation

Event	**Actions to be Taken**
• WBC < 3.5 x 10^9/L	Withhold until discussed with specialist team.
• Neutrophils < 2 x 10^9/L	Withhold until discussed with specialist team.
• Eosinophils > 0.5 x 10^9/L	Caution and increased vigilance required.
• Platelets < 150 x 10^9/L	Withhold until discussed with specialist team.
• Proteinuria 2+ or more	Check MSU: If infection present treat appropriately. If sterile and proteinuria 2+ or more persists, withhold until discussed with specialist.
• Rash (usually itchy) or oral ulceration	Withhold until discussed with specialist team.
• Abnormal bruising or severe sore throat	Check FBC immediately and withhold until results are available.

Please note: A rapidly increasing or decreasing trend in any values should prompt caution and extra vigilance

Results should be recorded in the patient's shared care monitoring record booklet, if issued

Adverse effects, Precautions and Contra-indications

Sodium aurothiomalate should be administered and monitored with extra caution in the elderly, those with moderate renal or hepatic impairment; history of urticarial, eczema or inflammatory bowel disease.
Blood dyscrasias including thrombocytopenia, pancytopenia, agranulocytosis, aplastic anaemia, leucopenia & neutropenia have been reported**.**

Proteinuria / haematuria: Transient mild proteinuria is common. If urinalysis reveals protein ++ or more, or blood ++ or more, perform MSU. If no infection present, request albumin creatinine ratio (in plain sterile bottle) and if >30 mg/mmol creatinine discontinue sodium aurothiomalate and refer to initiating specialist.
Anaphylactoid reactions have been reported rarely. Dizziness, nausea, vomiting, sweating and facial flushing characterize them. Sodium aurothiomalate treatment should be discontinued.
Diarrhoea- discontinue sodium aurothiomalate if severe or persistent.
Rash – often non-specific erythematous, dry and itchy - may occur early in therapy especially when full doses are given from the start. Antihistamines, steroid cover or temporary reduction of dose will control urticarial reactions. Discontinue sodium aurothiomalate and refer to specialist.
Mouth ulcers / stomatitis: if mild consider mouthwashes. If persistent or severe discontinue sodium aurothiomalate and refer to specialist.
Dyspnoea and dry cough: pulmonary complications are rare but potentially serious - refer to specialist.

Contraindications include:

- Hypersensitivity to sodium aurothiomalate
- Systemic lupus erythematosus
- Exfoliative dermatitis
- Porphyria
- Necrotising enterocolitis
- Significant pulmonary fibrosis
- Severe renal or hepatic impairment
- History of blood dyscrasias
- History of blood disorders or marrow aplasia

Pregnancy/Breastfeeding: therapy should be stopped when pregnancy is confirmed or suspected -refer to initiating specialist. Significant amounts of sodium aurothiomalate are excreted in breast milk therefore breast feeding should be avoided.

Common Drug Interactions

Phenylbutazone: risk of hepatotoxicity
High dose aspirin: risk of hepatotoxicity
ACE inhibitors: increased risk of anaphylaxis
Penicillamine: concomitant use not recommended

Communication

For any queries relating to this patient's treatment with sodium aurothiomalate, please contact the consultant named at the top of this document.

This information is not inclusive of all prescribing information, potential adverse effects and drug interactions

Please refer to full prescribing data in the SPC or the BNF

References

GMC: Prescribing guidance: Shared care www.gmc-uk.org/guidance/ethical_guidance/14321.asp(accessed 20/10/2014)

NMC : Standards of proficiency for nurse and midwife prescribers http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-proficiency-nurse-and-midwife-prescribers.pdf (accessed 3/11/2014)

SPC Myocrisin : http://www.medicines.org.uk/emc/medicine/18613

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Date prepared: March 2015 Date for review: March 2018

Chakravarty, K., McDonald, H., Pullar, T. et al. (2008) BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy in consultation with the British Association of Dermatologists. *Rheumatology* **47**(6), 924-925.