Shared Care Protocol

Intramuscular Sodium Aurothiomalate (Gold) for Rheumatoid Arthritis

<table>
<thead>
<tr>
<th>Protocol No. 7</th>
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<tbody>
<tr>
<td><strong>General guidance</strong></td>
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</table>
| **Licensed indication** | 1. Active progressive rheumatoid arthritis  
2. Progressive juvenile chronic arthritis especially if polyarticular or seropositive |
| **Background information** | Gold’s mode of action in rheumatoid arthritis is not fully understood. |
| **Contra-Indications:** | • Severe renal or hepatic disease.  
• Patients with a history of blood dyscrasias, exfoliative dermatitis or systemic lupus erythematosus.  
• Pregnancy and breast-feeding. |
| **Dosage regimen** | **Adults:** An initial intramuscular 10mg test dose in hospital (patient observed for at least 30 minutes) followed by weekly intramuscular doses of 50mg until there is definitive evidence of remission. Benefit is not to be expected until about 300 to 500mg has been given; it should be discontinued if there is no remission after 1g has been given.  
In patients who do respond, the interval between injections is then gradually increased to 4 weeks and the treatment is continued for up to 5 years after complete remission.  
If relapse occurs discuss with rheumatology (the dosage frequency may be immediately increased to 50mg weekly and only once control has been obtained should the dosage frequency be decreased; if no response is seen within 2 months, alternative treatment should be sought. It is important to avoid complete relapse since second courses of gold are not usually effective). |
| **Children:** | 1mg/kg body weight weekly to a maximum of 50mg weekly, the intervals being gradually increased to 4 weeks according to response. A test dose is given corresponding to one-tenth to one-fifth of the calculated dose. |
| **Side effects** | Mucocutaneous: mouth ulcers may respond to dose reduction, stop drug and discuss if severe  
Rash usually itchy stop drug. It may be possible to reintroduce at lower dose if results are normal, but discuss first.  
Sore throat or abnormal bruising withhold drug until FBC known  
Diarrhoea (very rare) stop drug. |
| **Drug Interactions** | Increased risk of toxicity with other nephrotoxic and myelosuppressive drugs. Aspirin-induced hepatotoxicity may be exacerbated.  
ACE inhibitors may increase the risk of anaphylactoid reactions.  
Sodium aurothiomalate not listed in BNF Appendix 1. |
### Monitoring

**Baseline monitoring:** (by Rheumatology Dept)
- FBC, Diff*, U&Es, Creatinine, LFTs, Urinalysis and Chest X-ray

**Ongoing monitoring:** (via GP)

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
<th>Action</th>
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<tbody>
<tr>
<td><strong>FBC &amp; Diff</strong></td>
<td>WBC &lt; 4 x 10^9/L Neutrophils &lt;2 x 10^9/L Platelets &lt;150 x 10^9/L Rising eosinophilia or Sequential fall of &gt;10% in 3 consecutive counts.</td>
<td>Stop Drug and discuss</td>
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Results need not be available before injection is given as long as the results of the previous test are. If sore throat or abnormal bruising develops, withhold drug until FBC known.

<table>
<thead>
<tr>
<th>Test</th>
<th>Test Result</th>
<th>Action</th>
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<tbody>
<tr>
<td><strong>Urinalysis</strong></td>
<td>Persistent + on more than 1 occasion</td>
<td>Stop drug unless MSU shows infection</td>
</tr>
<tr>
<td></td>
<td>+ +/ + + +</td>
<td>Stop drug and discuss</td>
</tr>
<tr>
<td><strong>Proteinuria</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Haematuria</strong></td>
<td>- +/ + +</td>
<td>Very common. Usually due to NSAIDs, occasionally GU pathology. If no proteinuria continue gold.</td>
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<tr>
<td><strong>LFTs (inc ALT)</strong></td>
<td>&gt; TWICE upper limit of normal ALT and Alk Phos.</td>
<td>Stop drug and discuss</td>
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<tr>
<td><strong>Chest X-ray</strong></td>
<td>annual</td>
<td>To be done by Secondary Care</td>
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Please note that in addition to absolute values for haematological indices, a rapid fall or consistent downward trend in any values should prompt caution and extra vigilance.

### Responsibilities of Secondary Care

- To initiate Sodium aurothiomalate in line with dosage regime and undertake baseline monitoring.
- To send the *Shared Care Agreement Form – Accredited* to the GP.
- To provide a patient information leaflet indicating the risks and benefits associated with Sodium aurothiomalate therapy. To confirm patient understanding and consent to treatment.
- To advise the patient on potential side effects (particularly any unexplained pruritis, metallic taste, sore throat or tongue, buccal ulceration, breathlessness and dry cough or easy bruising, purpura, epistaxis, bleeding gums, menorrhagia or diarrhoea) and the action to be taken should they occur.
- To inform the patient of the need for blood monitoring.
- To undertake an annual chest X-ray.

### Responsibilities of patients/carers

- To attend hospital and GP clinic appointments. Failure to attend will result in the medication being stopped.
- To report any adverse events immediately (particularly any unexplained pruritis, metallic taste, sore throat or tongue, buccal ulceration, breathlessness and dry cough or easy bruising, purpura, epistaxis, bleeding gums, menorrhagia or diarrhoea) to their specialist or GP.

### Responsibilities of Primary Care

- To monitor and prescribe Sodium aurothiomalate in collaboration with the specialist and follow these guidelines.
- To ask patient about adverse effects.

### Contact Details

If stopping the medication or needing advice please contact:
- 01873 732046 (Rheumatology Helpline North) or 01633 656251 (Rheumatology Helpline South)
- In an emergency a Clinical Nurse can be bleeped via the Nevill Hall Hospital Switchboard on the number 432.

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* Differential white cell count and platelet count