Sodium aurothiomalate (Myocrisin®)
Intramuscular gold injection for treatment of rheumatoid arthritis

Aim of treatment

Gold injection is a disease-modifying anti-rheumatic drug. This is a long term treatment, The earliest initial response is at 6-12 weeks.

Indication: Treatment of adults with rheumatoid arthritis.

A summary of prescribing information is provided on page 4.

Specialist responsibilities

- Decision to prescribe gold injection.
- Discuss benefits and side effects of treatment with patient or patient’s carers including, where appropriate, risks associated with pregnancy and need for reliable method of contraception.
- Refer patient to specialist nurse service where appropriate (eg. new patient) for advice on taking the drug, its cautions, side effects associated with treatment, monitoring requirements and the timing of re-assessment and by whom.
- Ascertain immune status by enquiring about history of chickenpox. Measurement of antibodies to varicella-zoster virus is not recommended.
- Issue a booklet for recording test results to patient.
- Specify review dates.
- Prompt verbal communication followed up in writing to GP of changes in treatment or monitoring requirements, results of monitoring, assessment of adverse events or when to stop treatment. Urgent changes to treatment should be communicated by telephone to GP.
- Reporting adverse events to CHM.

General practitioner responsibilities

If GP has agreed to share care:

- Prescribe intramuscular gold injection after communication with specialists.
- Conduct baseline tests - FBC, renal and liver function tests and urine test for protein.
- Administer test dose – observe patient for one hour. Take appropriate action if patient develops a rash.
- Check patient for rash and ask about mouth ulceration before subsequent doses. Observe patient for 30 minutes after each dose, check for rash. Take appropriate action if symptoms reported.
- Conduct monitoring of FBC, urinalysis, liver and renal function tests and CRP throughout treatment as specified. Review results and take any necessary action.
- Take appropriate action if patient reports sign(s) or symptom(s) listed under Monitoring.
- Be aware of criteria for referral to Rheumatology team.
- Respond to advice from secondary care on dose changes and frequency of monitoring.
- Report to and seek advice from specialist on any aspect of patient care of concern to GP which may affect treatment. Prompt referral to specialist if there is a change in patient’s health status.
- Report adverse events to specialist.
- Stop treatment in case of a severe adverse event or as per shared care guideline.

### Monitoring

**Monitoring prior to starting therapy – general practice**

FBC, renal and liver function tests and urine test for protein

**Monitoring during treatment – general practice**

1. **Administration of dose**
   
   1a. **Test dose:** Patient should remain under medical observation for one hour following test dose. If patient’s reaction includes low blood pressure, lie patient down, elevate legs and consider anaphylaxis measures if appropriate – this is very rare. If rash develops over next few days, do not administer further gold and inform Rheumatology team.

   1b. **Subsequent doses**

   **Before each dose:** Inspect skin for a rash and ask patient about presence of mouth ulcers. If either is present, withhold treatment and contact Rheumatology team.

   **After giving each dose:** Patient should remain under medical observation for 30 minutes. If rash develops, do not give further gold and inform Rheumatology team.

2. **Laboratory values**

<table>
<thead>
<tr>
<th>Tests</th>
<th>Frequency of monitoring</th>
<th>Guidance</th>
<th>Action to be taken by GP</th>
</tr>
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<tbody>
<tr>
<td><strong>FBC</strong></td>
<td>Before each injection</td>
<td>- If <strong>WCC</strong> falls on 3 successive occasions or &lt;3.5 x 10^9/l&lt;br&gt;- If <strong>neutrophils</strong> fall on 3 successive occasions or &lt;2.0 x 10^9/l&lt;br&gt;- If <strong>platelets</strong> fall on 3 successive occasions or &lt;150 x 10^9/l&lt;br&gt;- If <strong>eosinophils</strong> &gt;0.5 x10^9/l</td>
<td>If concerned about sequential drops in FBC indices (possibly still within the normal range) consider an early retest If count(s) meet specified criteria, stop treatment and refer to Rheumatology team</td>
</tr>
<tr>
<td><strong>LFTs</strong></td>
<td>If AST or ALT &gt; two times ULN</td>
<td></td>
<td>If small rise in AST or ALT, early next test. If &gt;3 fold rise, stop treatment, refer to Rheumatology team</td>
</tr>
<tr>
<td><strong>Creatinine and U&amp;Es</strong></td>
<td>Cr &gt;30% of baseline</td>
<td></td>
<td>Stop treatment and refer to Rheumatology team</td>
</tr>
<tr>
<td><strong>Urinalysis</strong></td>
<td>Before each injection</td>
<td>If proteinuria 2+ or more</td>
<td>-Send MSSU to exclude infection. &lt;br&gt;-If sterile and 2+ proteinuria or more persists, <strong>stop treatment</strong> and arrange 24 hr collection for protein. &lt;br&gt;- Results will vary according to the type of dipstick used, sensitivity and whether the patient is dehydrated or well perfused. &lt;br&gt;- 24-hour urinary protein below 0.3g per 24 hours is normal. Above 0.5g per 24 hours <strong>stop treatment</strong>. Discuss with rheumatologist. (Do not stop if only trace of protein).</td>
</tr>
<tr>
<td><strong>CRP</strong></td>
<td>Every three months</td>
<td>If CRP high, consider infection</td>
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1. The British Society of Rheumatology guidelines (2008) state that provided blood results are stable, the results of the FBC need not be available before the injection is given but must be available before the next injection.
3. Signs and symptoms
Severe reactions are reported in up to 5% of patients on gold therapy. Patients MUST report pruritus, sore throat or tongue, buccal ulceration, fever, rash, purpura, epistaxis, bleeding gums, menorrhagia, diarrhoea, unexpected bruising or bleeding, infection, and any unexplained illness. Breathlessness or cough MUST also be reported.

Action to be taken by GP:
See patient with any of the signs or symptoms listed above within 24 hours for full blood count and liver function tests.

- Stop treatment and refer if:
  - Rash (usually itchy)
  - Abnormal bruising
  - Severe sore throat
  - Severe oral ulceration
  - Unexplained illness including severe nausea, vomiting or diarrhoea

Do not stop treatment prior to surgery unless significant risk of infection.

Contact Microbiology if a patient, not known to be immune to chickenpox, comes into contact with shingles or chickenpox, for advice on whether zoster immune globulin or other treatment is indicated.

### Patient responsibilities

Patients:
- MUST report pruritus, sore throat or tongue, buccal ulceration, metallic taste, fever, rash, purpura, epistaxis, bleeding gums, menorrhagia, diarrhoea, unexpected bruising or bleeding, infection, and any unexplained illness to their GP and/or specialist. Breathlessness or cough MUST also be reported.
- Report any other adverse effect to their GP and/or specialist whilst being treated with gold injection.
- Ensure that they have a clear understanding of their treatment.
- Ensure they attend for monitoring requirements.
- Be aware that treatment will be stopped if patient does not attend for monitoring.

### Back-up advice and support

<table>
<thead>
<tr>
<th>Contact details</th>
<th>Telephone No</th>
<th>E-mail address</th>
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</thead>
<tbody>
<tr>
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Guideline updated by Clinical Effectiveness Team, Public Health, NHS Devon in consultation with local specialists and GPs

For non-clinical enquiries: clinicaleffectiveness.devonpct@nhs.net
Supporting Information

This guideline highlights significant prescribing issues, not all prescribing information and potential adverse effects are listed. Please refer to SPC/data sheet for full prescribing data.

**Dose**

- 10mg test dose (to test for hypersensitivity and rash). Patient should be observed for one hour.
- A 50mg dose is given one week later then at intervals of one week until total 1g given (excluding the test dose) and thereafter monthly. (Do not expect benefit until 600-1000mg given). The usual maintenance dose is 50mg monthly. NB dosing regimen differs from the product SPC.
- Dosing schedule will change according to patient response and recommendation from the Rheumatology team.
- Administration: should only be administered by deep intramuscular injection followed by gentle massage of the injection area.

**Contraindications**

- Previous serious reaction or anaphylaxis to phenylmercuric nitrate.
- Pregnancy: the safety of intramuscular gold injection in pregnancy has not been established. Patients of child-bearing age should be advised to use a reliable method of contraception during treatment. When planning a pregnancy it is important that both men and women on this drug discuss medication with the Rheumatology team (at least six months before conception) since all drugs can potentially affect the unborn child.
- Severe renal or hepatic impairment (see also Precautions).
- History of blood dyscrasias or marrow aplasia, exfoliative dermatitis or systemic lupus erythematosus.

**Precautions**

- Elderly – monitor with extra caution.
- Moderate renal or hepatic impairment.
- History of urticaria, eczema or inflammatory bowel disease.
- Blood dyscrasias are most likely to occur when between 400mg and 1g of gold have been given, or between the 10th and 20th week of treatment, but can also occur with much lower doses or after only 2-4 weeks of therapy.
- Lactation: see SPC for further information

**Side effects**

**Common/uncommon:**

- Mouth ulcers, metallic taste
- Rash – mild scaly rash to severe dermatitis; may not necessitate withdrawal of drug. Significant skin complications are almost exclusively pruritic.
- Hypersensitivity reactions
- Bone marrow suppression
- Proteinuria

**Interactions**

- ACE inhibitors: flushing and hypotension reported with concurrent use.
- Penicillamine: avoid concurrent use (increased risk of toxicity).
**Vaccines**

- Live vaccines should be avoided. These include measles, mumps and rubella; BCG; poliomyelitis – oral Sabin vaccine; yellow fever; typhoid – oral.
- Flu and pneumococcal vaccines may be given.
- Passive immunisation should be carried out using Varicella Zoster Immunoglobulin (VZIG) in non-immune patients if exposed to chickenpox or shingles. See local guidance page 3.

For additional information refer to the British Society of Rheumatology guidance on vaccinations for immuno-suppressed patients at: [http://www.rheumatology.org.uk/includes/documents/cm_docs/2009/v/vaccinations_in_the_immunocompromised_person.pdf](http://www.rheumatology.org.uk/includes/documents/cm_docs/2009/v/vaccinations_in_the_immunocompromised_person.pdf)

**Pregnancy and lactation**

See Contraindications section and SPC for further information

**Product information and notes**

- Do not use a darkened solution (more than pale yellow).
- Store any injections below 25°C and protect from light.
- Injection contains phenylmercuric nitrate as a preservative

Sodium aurothalamate 50mg in 0.5ml injection (cost per amp: £11.23); 10mg in 0.5ml injection (cost per amp: £3.80).

**Date ratified by Effective Practice Committee: February 2011.**
**Review date: November 2013**
Shared Care Agreement Letter - Consultant Request

To: Dr………………………………………………………………………………………………

Practice Address: ……………………………………………………………
………………………………………………………………………………
………………………………………………………………………………

DIAGNOSED CONDITION: …………………………………………………………………

I recommend treatment with the following drug: …………………………………………………

I request your agreement to sharing the care of this patient according to the North and East Devon Health Community Shared Care Prescribing Guidelines for this drug.

Principles of shared care:

**GPs are invited to participate. If GP is not confident to undertake these roles, then they are 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 practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and accepted by them.

The doctor who prescribes the medication has the clinical and legal responsibility for the drug and the consequences of its use.

<table>
<thead>
<tr>
<th>Signed:</th>
<th>Date:</th>
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<tbody>
<tr>
<td>Consultant name:</td>
<td></td>
</tr>
<tr>
<td>Contact telephone number:</td>
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</tbody>
</table>

**GP RESPONSE**

I agree/ do not agree* to share the care of this patient in accordance with the Shared Care Guideline.

Signed: ……………………………………… Date: ………………………………………

GP name: ……………………………………… *Delete as appropriate