Sodium Aurothiomalate (Myocrisin) - for treatment of rheumatological inflammatory diseases

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE
This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Sodium Aurothiomalate (Myocrisin) can be shared between the specialist and general practitioner or non-medical prescriber in primary care (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In that case, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. **If a specialist asks the GP to prescribe drugs for this treatment, the GP should reply to this request as soon as practicable.**

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with rheumatological inflammatory diseases are under regular specialist follow-up. This provides an opportunity to discuss and to monitor drug therapy.

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

RESPONSIBILITIES and ROLES

<table>
<thead>
<tr>
<th>Specialist responsibilities</th>
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<tr>
<td>• Ensure FBC, liver and renal function are within normal parameters to allow Sodium Aurothiomalate (Myocrisin) to commence.</td>
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<td>• If abnormalities found at baseline inform GP as soon as possible.</td>
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<td>• Initiate treatment with Sodium Aurothiomalate (Myocrisin) or advise GP on initiating treatment.</td>
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<td>• Discuss the benefits and side effects of treatment with the patient and inform GP this has occurred.</td>
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<td>• Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient.</td>
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<td>• Review the patient's condition and monitor response to treatment regularly where indicated.</td>
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<td>• Advise GP if monitoring is needed, and the frequency.</td>
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<td>• Monitor any other parameters considered necessary, or advise GP on which to monitor.</td>
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<td>• Communicate promptly with the GP when treatment is changed or needs to be changed by the GP, any results of the monitoring undertaken, and assessment of adverse events.</td>
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<td>• Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.</td>
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<td>• Advise GPs on when to stop treatment (if appropriate).</td>
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<td>• Report adverse events to the MHRA via Yellow Card Scheme.</td>
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<td>• Ensure that clear backup arrangements exist for GPs to obtain advice and support.</td>
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Any queries relating to this Shared Care Protocol contact the Clinical Effectiveness Pharmacist (01592) 226915

Document approved by NHS Fife Area Drugs & Therapeutics Committee on behalf of NHS Fife. Date: February 2013

Ishtiaq Mohammed, Clinical Effectiveness Pharmacist
General Practitioner responsibilities

- Reply to the request for shared care as soon as practicable.
- Prescribe and administer Sodium Aurothiomalate (Myocrisin) at the dose recommended.
- Adjust the dose as advised by the specialist.
- Monitor any parameters considered necessary, if agreed with the specialist to do so.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
- Refer patient to specialist if his or her condition deteriorates.
- Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
- Report adverse events to the specialist and to the MHRA via the Yellow Card Scheme.

Patient’s role

1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
3. Report any adverse effects to the specialist or GP in particular sore throats, fever and severe malaise.

BACK-UP ADVICE AND SUPPORT

<table>
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<tr>
<th>Contact details</th>
<th>Telephone No.</th>
<th>Email address:</th>
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<tbody>
<tr>
<td>Specialist:</td>
<td>01592 648193</td>
<td><a href="mailto:janegibson@nhs.net">janegibson@nhs.net</a></td>
</tr>
<tr>
<td>Rheumatology Dept</td>
<td>01592 265967 (fax)</td>
<td><a href="mailto:helenharris@nhs.net">helenharris@nhs.net</a>, <a href="mailto:johnmclaren@nhs.net">johnmclaren@nhs.net</a>, <a href="mailto:sharoncullinane@nhs.net">sharoncullinane@nhs.net</a></td>
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<tr>
<td>Other:</td>
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SUPPORTING INFORMATION (taken from the SPC)

Licensed indications

Active joint inflammation usually supported by indices of inflammation.

Dosage and Administration

By deep intramuscular injection:
10mg test dose then 50mg weekly until definite evidence of remission (benefit not expected until 300-500mg given). Discontinue if no benefit after 1000mg.

In patients who respond, interval is increased gradually to 4 weeks. If relapse, immediately increase frequency to 50mg weekly and only decrease when control obtained. If no control within 2 months, alternative therapy should be considered.

Contraindications and precautions for use

Severe renal or hepatic impairment, history of blood disorders or bone marrow aplasia, exfoliative dermatitis, systemic lupus erythematosus, necrotising enterocolitis, significant pulmonary fibrosis, porphyria.

Could be used in pregnancy if benefit is considered to outweigh possible risk (no controlled studies in women/animals). Consider reducing the dose and frequency.
Avoid breast feeding.
Live vaccines are not recommended.

**Side Effects (also state any specific side-effects which require the consultant to be notified)**

- Common: mouth ulcers, skin rash or itch, proteinuria, blood disorders (e.g. thrombocytopenia).
- Rare: colitis, peripheral neuritis, pulmonary fibrosis, hepatotoxicity (LFTs > 2-3 times upper limit of normal), nephrotic syndrome and alopecia.
- Anaphylactoid or nitroid reactions occur rarely just a few minutes after the injection and are characterised by dizziness, nausea, vomiting, sweating, and facial flushing.

For a complete list of side effects see BNF/ Summary of product Characteristics.

**Treatment should be withheld and the Rheumatology Department contacted if:**

- NEUTROPHILS <1.5x 10^9
- PLATELETS < 100x 10^9
- 2 + PROTEINURIA / HAEMATURIA ON > 1 OCCASION, with negative MSU.
- RASH or MOUTH ULCERATION
- ABNORMAL BRUISING / SORE THROAT (urgent F.B.C. required)

**Monitoring (State specific monitoring to be undertaken by the GP / Consultant) see FRDU blood monitoring forms (ADTC website)**

**Rheumatologist responsibilities:**
FBC, liver and renal function are within normal parameters to allow Sodium Aurothiomalate (Myocrisin) to commence.

**General Practitioner responsibilities:**
- While taking Sodium Aurothiomalate (Myocrisin) patients will require a FBC and URINALYSIS at the time of each injection. It is permissible to work one F.B.C. in arrears. After 6 months of uncomplicated treatment then FBC can be reduced to monthly & urinalysis before each injection.
- Patients should be specifically asked for the presence of a rash or mouth ulceration prior to each injection.

**Drug Interactions**
- Flushing and hypotension have been reported when Sodium Aurothiomalate (Myocrisin) is administered with ACE inhibitors.
- Avoid use of Penicillamine with Sodium Aurothiomalate (Myocrisin).
- Avoid concomitant use of live vaccines.

For a complete list of drug interactions please see the BNF / Summary of Product Characteristics.

**Cost (March 2012)**

Myocrisin injection
- 0.5ml (10mg) amp = £3.80
- 0.5ml (50mg) amp = £11.23