Injectable Gold
(Sodium aurothiomalate, Myocrisin)

Traffic light classification - Amber 1

Information sheet for Primary Care Prescribers

Part of the Shared Care Protocol: Management of Rheumatological Conditions with Disease-Modifying Anti Rheumatic Drugs in Adults

Indications
Rheumatoid arthritis - licensed.

Therapeutic Summary
Myocrisin® (sodium aurothiomalate) is the injectable (IM) form of gold. It can induce a remission or partial remission in patients with inflammatory arthritis. Clinical improvement may take up to 6 months. NSAID and simple analgesics may need to be continued. Patient reported adverse effects usually occur early in therapy, but please see explicit criteria for review below. This drug is now rarely used.

Products available
Myocrisin® 100mg/ml - 50mg in 0.5ml ampoules
Myocrisin® 20mg/ml - 10mg in 0.5ml ampoules

Dosage and route of administration
- A typical dosage regimen would be 50mg weekly with dosage intervals increased in stages to 50mg monthly, i.e. 50mg alternate weeks for 3 months then monthly thereafter.
- Doses are given by deep intramuscular injection followed by gentle massage of the area.
- The patient should remain under medical observation for 30 minutes after the injection.

Duration of treatment
All DMARDS are long term treatments. Benefit with sodium aurothiomalate should not be expected until a cumulative dose of at least 500mg has been given.

Monitoring Requirements and Responsibilities
Pre-treatment assessment to be performed by the specialist and will include:
- FBC, urinary dipstick for protein, U&Es, LFTs

Ongoing monitoring:

<table>
<thead>
<tr>
<th>Time period in treatment</th>
<th>Frequency of monitoring</th>
<th>Tests to be done</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>FBC</td>
</tr>
<tr>
<td>0-6 weeks</td>
<td>Fortnightly</td>
<td>✔</td>
</tr>
<tr>
<td>6 weeks – 3 months</td>
<td>Monthly</td>
<td>✔</td>
</tr>
<tr>
<td>&gt;3 months and stable dose for 6 weeks</td>
<td>3 monthly*</td>
<td>✔</td>
</tr>
<tr>
<td>Any dose increase</td>
<td>2 weeks post dose increase then revert to above protocol</td>
<td>✔</td>
</tr>
<tr>
<td>All patients</td>
<td>At the time of every injection</td>
<td>✔</td>
</tr>
</tbody>
</table>

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REVIEW DATE June 2019
DATE APPROVED BY THE NOTTINGHAMSHIRE APC: May 2017
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Nottinghamshire Area Prescribing Committee

- Before every injection, patients should be asked about the presence of any rash or mouth ulcers.
- GP to assess and manage cardiovascular risk factors – patient at higher risk of cardiovascular events due to rheumatological disease activity.
- Routine influenza and pneumococcal vaccination are highly recommended.

No additional monitoring requirements are required in primary care for patients receiving additional biological therapy including anti-TNF therapy.

Explicit criteria for review and discontinuation of the medicine – Other benchmark values may be set by secondary care in specific clinical circumstances. This will be communicated by secondary care.

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC&lt;3.5x10^9/l</td>
<td>Withhold until discussed with rheumatology specialist team.</td>
</tr>
<tr>
<td>Neutropenia&lt;2.0x10^9/l</td>
<td>Withhold until discussed with rheumatology specialist team.</td>
</tr>
<tr>
<td>Eosinophilia&gt;0.5x10^9/l</td>
<td>Caution and increased vigilance required.</td>
</tr>
<tr>
<td>Platelets&lt;150x10^9/l</td>
<td>Withhold until discussed with rheumatology specialist team.</td>
</tr>
<tr>
<td>2+ proteinuria or more</td>
<td>Check MSSU: If infection present treat appropriately. If sterile and 2+ proteinuria or more persists, withhold until discussed with rheumatology specialist team.</td>
</tr>
<tr>
<td>Rash (usually itchy) or oral ulceration</td>
<td>Withhold until discussed with rheumatology specialist team.</td>
</tr>
<tr>
<td>Abnormal bruising</td>
<td>Check FBC immediately and withhold until results are available.</td>
</tr>
<tr>
<td>Dizziness, nausea, vomiting, sweating, and facial flushing within the first ten minutes following drug administration.</td>
<td>Likely anaphylactoid or nitritoid reaction. Withhold until discussed with rheumatology specialist team.</td>
</tr>
</tbody>
</table>

In addition to absolute values for haematological or biochemical indices a rapid fall or rise or consistent downward or upward trend in any value should prompt caution and extra vigilance.³

For a full list of side effects refer to the BNF or Summary of Product Characteristics

IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE RHEUMATOLOGY SPECIALIST TEAM.

Relevant Contraindications¹²³⁴

- Pregnancy and lactation.
- Severe renal or hepatic disease.
- Acute porphyria.
- Live vaccines (see BNF or Immunisation against infectious disease - 'The Green Book' available at www.dh.gov.uk): Avoid as severe antigenic reactions may occur if a live vaccine is given concurrently. N.B. Routine influenza and pneumococcal vaccinations are highly recommended.

³ For a full list of side effects refer to the BNF or Summary of Product Characteristics

⁴ IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE RHEUMATOLOGY SPECIALIST TEAM.
Relevant precautions$^{1,2,3,4}$
- Anaphylactoid or nitritoid reactions are rare but may occur after any course of therapy within the first ten minutes following drug administration. Dizziness, nausea, vomiting, sweating, and facial flushing characterize them. Sodium aurothiomalate treatment should be discontinued.
- Elderly, moderate renal or hepatic impairment.

Clinically relevant medicine interactions and their management$^{1,2,4}$
- Caution is needed in patients treated concomitantly with angiotensin-converting enzyme inhibitors due to an increased risk of severe anaphylactoid reaction in these patients.

For a full list of drug interactions refer to the BNF or Summary of Product Characteristics

Information given to patient$^4$
- Patients should be warned to report immediately the appearance of diarrhoea, sore throat, fever, infection, unexplained bleeding and bruising, purpura, mouth ulcers, metallic taste, rash, breathlessness or cough.
- The patient will also be given an approved drug information leaflet from Arthritis Research UK. Further copies available at www.arthritisresearchuk.org

Patient’s roles and responsibilities
- The patient will report any suspected adverse reactions (as above) to the GP for assessment.

References