Effective Shared Care Agreement (ESCA)

Sodium aurothiomalate (IM gold)

(Myocrisin)

ESCA: For the treatment of rheumatoid arthritis or psoriatic arthritis

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 for rheumatoid arthritis or psoriatic arthritis can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you 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.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with rheumatoid arthritis or psoriatic arthritis are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

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

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Confirm the diagnosis of rheumatoid arthritis or psoriatic arthritis.
2. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
3. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made.
4. Do baseline monitoring prior to initiation of sodium aurothiomalate.
5. Initiate treatment and stabilise dose of sodium aurothiomalate.
6. Review the patient's condition and monitor response to treatment regularly
7. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
8. Report serious adverse events to the MHRA
9. Ensure clear backup arrangements exist for GPs, for advice and support (Please complete details below)

General Practitioner responsibilities						
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days						
2. Prescribe Myocrisin (IM gold)at the dose recommended						
3. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement						
GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care
4. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist						
5. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment						
6. Refer back to specialist if condition deteriorates						
7. Report serious adverse events to specialist and MHRA						
8. Stop treatment on advice of specialist						

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment
2. Share any concerns in relation to treatment with sodium aurothiomalate with the specialist, clinical nurse specialist or GP
3. Report any adverse effects to the specialist or GP whilst taking sodium aurothiomalate
4. Attend regular outpatient appointments with the specialist

BACK-UP ADVICE AND SUPPORT

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

SUPPORTING INFORMATION

<table>
<tr><td>Indication</td><td>Sodium aurothiomalate is used in the management of active progressive rheumatoid arthritis and progressive juvenile chronic arthritis especially if polyarticular or seropositive.</td></tr>
<tr><td>Dosage and Administration

BSR Recommendations</td><td>Sodium aurothiomalate should be administered only by deep intramuscular injection followed by gentle massage of the area. The patient should remain under medical observation for a period of 30 minutes after drug administration.

<table>
<tr><td>Week 1</td><td>10 mg test dose to ensure no allergic response occurs</td></tr>
<tr><td>Weeks 2 to 20</td><td>50 mg weekly. If early response, gradually reduce frequency 50 mg every two weeks</td></tr>
<tr><td>Week 20+</td><td>1000 mg cumulative dose. If response, reduce frequency to 50 mg every two weeks. If no response abandon therapy. Responders: gradually reduce to maintenance dose of 50 mg every month</td></tr>
</table>

With full remission the interval between injections should be increased progressively to three, four and then, after 18 months to 2 years, to six weeks.

If after reaching a total dose of 1 g (excluding the test dose), no major improvement has occurred and the patient has not shown any signs of gold toxicity, six 100 mg injections may be administered at weekly intervals. If no sign of remission occurs after this time other forms of treatment are to be considered.</td></tr>
<tr><td rowspan="2">Renal Impairment</td><td>Mild
Moderate</td><td>Use with caution</td></tr>
<tr><td>Severe</td><td>Avoid</td></tr>
<tr><td rowspan="2">Hepatic impairment</td><td>Mild
Moderate</td><td>Use with caution</td></tr>
<tr><td>Severe</td><td>Avoid</td></tr>
<tr><td>Contra-indications / Special precautions</td><td>Contraindications
• Pregnancy
• Sodium aurothiomalate is contraindicated in patients with gross renal or hepatic disease, a history of blood dyscrasias, exfoliative dermatitis or systemic lupus erythematosus.
• The absolute contraindications should be positively excluded before considering gold therapy.
Caution
• As with other gold preparations, reactions which resemble anaphylactoid effects have been reported. These effects may occur after any course of therapy within the first ten minutes following drug administration. If anaphylactoid effects are observed, treatment with sodium aurothiomalate should be discontinued.
• Sodium aurothiomalate should be administered with extra caution in the elderly and in patients with a history of urticaria, eczema or colitis. Extra caution should also be exercised if phenylbutazone or oxyphenbutazone are administered concurrently.
• Before starting treatment and again before each injection, the urine should be tested for protein, the skin inspected for rash and a full blood count performed, including a numerical platelet count (not an estimate) and the readings plotted. Blood dyscrasias are most likely to occur when between 400 mg and 1 g 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.
• The presence of albuminuria, pruritus or rash, or an eosinophilia, are indications of developing toxicity. The sodium aurothiomalate should be withheld for one or two weeks until all signs have disappeared when the course may be restarted on a test dose followed by a decreased frequency of gold injections.
• A complaint of sore throat, glossitis, buccal ulceration and/or easy bruising or bleeding, demands an immediate blood count, followed if indicated, by appropriate treatment for agranulocytosis, aplastic anaemia and/or thrombocytopenia. Every patient treated with sodium aurothiomalate should be warned to report immediately the appearance of pruritus, metallic taste, sore throat or tongue, buccal ulceration or easy bruising, purpura, epistaxis, bleeding gums, menorrhagia or diarrhoea
• Live vaccines are not recommended in patients receiving sodium aurothiomalate</td></tr>
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Side Effects	Common	• Mouth ulcers • Nausea • Pruritus • Metallic taste
	Less Common	• Severe rash • Leucopoenia (WBC <3.5 and neutrophils <2.0) • Thrombocytopenia (platelets <120) • Proteinuria (>300 mg/L)
Monitoring **BSR Recommendations**	Pre-treatment Assessment	FBC, urinary dipstick for protein, U&E, creatinine, LFTs
	After commencing treatment	• FBC and urine for blood and protein at each injection • Ask patient about rash, mouth ulcers and itching • U&Es and LFTs every 2/12 or as clinically indicated
	Disease monitoring	Occasional ESR/CRP helps assessment
	Actions to be taken - British Society for Rheumatology recommendations	
	WBC<3.5x10^9/l	Withhold until discussed with specialist team.
	Neutropenia <2.0 x10^9/l	Withhold until discussed with specialist team.
	Eosinophilia>0.5x10^9/l	Caution and increase vigilance required
	Platelets<150x10^9/l	Withhold until discussed with specialist team.
	2+ proteinuria or more	Check MSSU: If infection present treat appropriately. If sterile and 2þ proteinuria or more persists, withhold until discussed with specialist team
	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.
	Dose reduction	For mouth ulcers, metallic taste and itch. Consider dose reduction
Drug Interactions	**Sodium aurothiomalate** has the following interaction information:	
	ACE Inhibitors	flushing and hypotension reported when sodium aurothiomalate given with ACE inhibitors
	Penicillamine	avoidance of sodium aurothiomalate advised by manufacturer of penicillamine (increased risk of toxicity)

References

- British Society for Rheumatology (BSR) guidelines
- Mycrisin Injection SmPC
- Sodium aurothiomalate BNF

I agree to participate in this shared care agreement for the treatment of the below named patient with sodium aurothiomalate for rheumatoid arthritis or psoriatic arthritis

General Practitioner
Name (please print)_____Signature _____Date_____

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant at: