

Sodium Aurothiomalate Effective Shared Care Agreement For use in Rheumatoid Arthritis

Section 1: Shared Care arrangements and responsibilities

Section 1.1 Agreement to transfer of prescribing of Sodium Aurothiomalate to GP

Patient details	Name:	
	Address:	
	Date of Birth:	
	NHS number: .	
Contact details Specialist: Address:		Agreement to shared care, to be signed by GP and Specialist before prescribing is transferred to GP
Email:		Specialist Signature:
Contact number:		Date:
GP		
Address:		GP Signature:
Email:		Date:
Contact number:		
Patient		Patient
Name:		Signature:
Contact number:		Date:

Section 1.2: Shared Care responsibilities

This shared care agreement outlines suggested ways in which the prescribing responsibilities can be shared between the specialist and GP. GPs are invited to participate. If the GP feels that undertaking the roles outlined in the shared care agreement is outside their area of expertise or has clinical concerns about the safe management of the drug in primary care, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient's health remains with the specialist. If a specialist asks the GP to prescribe, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between specialist, GP and patient.

If a specialist asks the GP to prescribe, the GP should reply to this request within 2 weeks

The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Responsibilities of the specialist initiating treatment

- Discuss with the patient options for treatment and the suitability of sodium aurothiomalate
- Discuss the potential benefits and side effects of treatment with the patient
- Undertake baseline tests: FBC, LFTs, U&Es, creatinine, urinary dipstick for protein
- Initiate sodium aurothiomalate treatment
- 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. Specialist attaches
 copy of Shared Care Agreement (SCA) from the trust intranet to printed letter.
- Titrate sodium aurothiomalate to an effective dose. If both GP and specialist feel it is appropriate, shared care may be initiated before the patient is stabilised on the effective dose, as long as the dose is stable until the next specialist appointment.
- Or commence treatment with sodium aurothiomalate and once patient is on a stable dose between visits, consider transfer of prescribing and monitoring to GP. .
- Ensure agreed signed shared care form has been received back from GP to indicate that the GP is in agreement with prescribing and monitoring.
- Ensure that this has been discussed with patient, and that patient has signed SCA form
- Regular follow-up of patient (at least annually)
- Communicate promptly with the GP when treatment is changed
- Advise GP on dosage adjustment and when and how to stop treatment
- Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition and ensure that clear backup arrangements exist for GPs to obtain advice and support
- Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the General Practitioner

- Prescribe sodium aurothiomalate
- Arrange and record on-going monitoring as agreed with specialist:
 - ➤ **FBC** at the time of each injection (results of FBC need not be available before each injection is given, but must be available before the next injection).
 - Urinalysis must be carried out before each injection.
- Ensure no drug interactions with other medicines
- Check patient is using adequate contraception
- Continued prescribing is appropriate for patients attending regular review
- Report adverse events to the MHRA (via Yellow Card)
- Administer influenza vaccine annually unless otherwise advised by the initiating specialist

- Check patient has had ONE DOSE of pneumococcal vaccine (revaccination is not recommended except every five years in patients whose antibody levels are likely to have declined more rapidly e.g. asplenia.) - see BNF or Green Book
- Passive immunisation using Varicella immunoglobulin (VZIG) should be considered in nonimmune patients if exposed to chickenpox or shingles.
- Ask about oral ulceration/sore throat, unexplained rash or unusual bruising at every consultation

Withhold sodium aurothiomalate and discuss with the specialist if:

- **WBC** $< 3.5 \times 10^9/L$
- Neutrophils < 2 x 10⁹/L
- Eosinophils $> 0.5 \times 10^9/L$
- Platelets <150 x 10⁹/L
- Proteinuria/blood ++ or more (Check MMSU: if infections present treat appropriately. If sterile and 2+ proteinuria or more persists, stop drug and discuss with specialist)
- Oral ulceration/sore throat/unexplained rash
- Abnormal bruising or sore throat (check FBC immediately and withhold until FBC results available)

Please note: A rapidly increasing or decreasing trend in any values should prompt caution and extra vigilance. Some patients may have abnormal baseline values, specialist will advise

Responsibilities of the patient

- To attend scheduled appointments with specialist and GP and for monitoring as detailed above
- Report any adverse effects to the specialist or GP.
- Share any concerns in relation to treatment.
- Report to the specialist or GP if they do not have a clear understanding of the treatment

Section 2: General Information on Sodium Aurothiomalate

Licensed Indication

Active progressive rheumatoid arthritis

Dosage and administration

An initial test dose of 10mg should be given in the first week followed by weekly doses of 50mg until signs of remission occur. At this point 50mg doses should be given at two week intervals until full remission occurs. 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 1g (excluding the test dose), no major improvement has occurred and the patient has not shown any signs of gold toxicity, six 100mg injections may be administered at weekly intervals. If no sign of remission occurs after this time other forms of treatment are to be considered

Contraindications

- Systemic lupus erythematosus
- Renal or hepatic disease
- History of blood dyscrasias
- Pregnancy/breastfeeding: therapy should be stopped when pregnancy is confirmed or suspected-refer to initiating specialist. Significant amounts of sodium aurothiomalate are excreted in breast milk and therefore lactating mothers should not breastfeed their infants.

Side effects

Proteinuria/haematuria: Transient mild proteinuria is common. If urinalysis reveals protein ++ or more, or blood ++ or more, perform MSU. If no infection present, request albumin creatinine ratio (in plain sterile bottle) and if >30mg mmol creatinine discontinue sodium aurothiomalate and refer to initiating specialist.

Diarrhoea- discontinue sodium aurothiomalate if severe or persistent.

Rash – often non-specific erythematous, dry and itchy- may occur early in therapy especially when full doses are given from the start. Antihistamines, steroid cover or temporary reduction of dose will control urticarial reactions. Discontinue sodium aurothiomalate and refer to specialist.

Mouth ulcers/stomatitis: if mild consider mouthwashes. If persistent or severe discontinue sodium aurothiomalate and refer to specialist.

Dyspnoea: pulmonary complications are rare but potentially serious - refer to specialist.

Drug Interactions¹

Caution is needed in patients treated concomitantly with sodium aurothiomalate and **angiotensin-converting enzyme inhibitors** due to an increased risk of severe anaphylactoid reaction in these patients.

Penicillamine- manufacturer advises avoidance with sodium aurothiomalate.

¹ BNF 66 September 2013-March 2014.