

# Sodium aurothiomalate injection

Rheumatology / Dermatology shared care guideline.

Specialist details	Patient identifier
Name: _____	
Location: _____	
Tel: _____	Date: _____

## Introduction

**Licensed indications:** active progressive rheumatoid arthritis, juvenile idiopathic arthritis.

**Unlicensed indications:** skin diseases including pemphigus, psoriatic arthritis.

## Adult dosage and administration

Sodium aurothiomalate should be administered only by deep intramuscular (IM) injection followed by gentle massage of the area.

A typical dose regimen may be: 10mg *test dose* (with 30 minutes observation to look for any signs of allergic reaction) followed by 20 - 50mg weekly until there is a significant response.

If no significant response is seen after a total cumulative dose of 1000mg has been given the efficacy should be questioned and alternative medicines considered.

In patients who respond, 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 weeks, four weeks and then, after 18 months to 2 years of remission, to six weeks.

Sodium aurothiomalate available as: 10mg/0.5mL injection, 50mg/0.5mL injection.

## Hospital specialist responsibilities

- Assess if the patient is suitable for treatment with sodium aurothiomalate.
- Agree shared care with patient's GP and document in patient's case notes.
- Provide the patient/carer with relevant (preferably written) information on use, side effects and need for monitoring of medication.
- Provide shared care monitoring record booklet if required.
- Undertake baseline tests as indicated in monitoring table.
- Review results of safety monitoring and request additional tests as required.
- Monitor disease response to treatment and need to continue therapy.
- Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.

Monitoring table		Hospital specialist	GP			Hospital specialist
Test	Indication	Pre-treatment baseline	During treatment			Annual review
			Until on stable dose for 6 weeks	Next 3 months	Thereafter	
FBC	Baseline assessment, dose adjustment	✓	Every 2 weeks	Every month	Every 3 months	As part of annual review or as clinically indicated
LFTs						
U&Es, eGFR						
ESR/CRP (Rheumatology only)	Disease activity scoring	Every 3 months				
Urinalysis	To assess for renal disease (proteinuria) or infection	✓	Must be carried out immediately before each injection			
Height & weight	Baseline assessment	✓	Not routinely required			If clinically indicated
Blood pressure	Baseline assessment, respiratory and TB screening	If clinically indicated				
Chest x-ray						
PFTs, TB screening if indicated						
Ask about oral ulceration, sore throat, unexplained rash or unusual bruising/bleeding		✓	At every consultation			✓

If a further DMARD is added as combination therapy, or the dose is increased, the initial starting schedule should be reinstated. There may be clinical circumstances where the frequency of monitoring may vary and this should be specified by the initiating specialist.

### GP responsibilities

- Prescribe sodium aurothiomalate and arrange for administration.
- Arrange and record ongoing monitoring as advised by specialist (see monitoring table), ensuring practice systems are in place to recall patients for monitoring blood tests.
- Prevent ongoing prescription if patient is not compliant with monitoring. Liaise with specialist if appropriate.
- Report any adverse drug reactions to the initiating specialist and the usual bodies (eg. MHRA/CHM).
- Ensure no drug interactions with other medicines.
- Ask about oral ulceration/sore throat; unexplained rash or unusual bruising at every consultation.

### Withhold sodium aurothiomalate and contact specialist if:

- WCC < 3.5 x 10<sup>9</sup>/L
- Neutrophils < 1.6 x 10<sup>9</sup>/L
- Unexplained eosinophilia > 0.5 x 10<sup>9</sup>/L
- Platelets < 140 x 10<sup>9</sup>/L
- **Urinalysis:** If proteinuria ++ and/or haematuria ++ or more, withhold, and check MSSU. If infection present, treat appropriately. If no infection present, withhold sodium aurothiomalate, check urine protein/creatinine ratio and discuss with specialist team.
- MCV > 105fL, (check B12 & folate & TFT)
- AST/ALT > 3 times the upper limit of normal (for results between 2 - 3 x ULN, continue sodium aurothiomalate, repeat bloods and seek specialist advice). Minor elevations of AST/ALT are common
- If renal impairment develops
- Unexplained fall in serum albumin
- Oral ulceration / sore throat
- Unexplained rash / abnormal bruising.

Normal reference range may vary slightly between labs.

Results should be recorded in the patient's shared care monitoring record booklet (where in use).

Please note an unusual fall or rise or a consistent downward or upward trend in any value should prompt review of the patient and extra vigilance. Some patients may have abnormal baseline values, specialist will advise.

## Adverse effects, precautions and contraindications

**Blood disorders:** thrombocytopenia, pancytopenia, agranulocytosis, aplastic anaemia, leucopenia and neutropenia have been reported.

**Sodium aurothiomalate should be administered and monitored with extra caution in** the elderly, those with moderate renal or hepatic impairment, history of urticarial eczema or inflammatory bowel disease.

**Proteinuria.** Transient mild proteinuria is common (see urinalysis in table above).

**Anaphylactoid** reactions have been reported

**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 and dry cough.** Pulmonary complications are rare but potentially serious - refer to specialist.

**Contraindications include:**

- Systemic lupus erythematosus
- Exfoliative dermatitis
- Necrotising enterocolitis
- Significant pulmonary fibrosis
- Severe renal or hepatic impairment
- History of blood dyscrasias.

**Pregnancy / contraception.** Women of childbearing potential receiving sodium aurothiomalate should be advised to use effective contraception. Patients discovered or planning to become pregnant should be referred to the initiating specialist at the earliest opportunity.

**Breastfeeding.** Women must not breastfeed while receiving sodium aurothiomalate.

## Common drug interactions

**ACE inhibitors:** increased risk of anaphylactoid reactions.

**Aspirin (high dose):** risk of hepatotoxicity.

**Penicillamine:** concomitant use not recommended.

**Phenylbutazone:** risk of hepatotoxicity.

## Communication

For any queries relating to this patient's treatment with sodium aurothiomalate, please contact the specialist named at the top of this document

This information is not inclusive of all prescribing information and potential adverse effects.  
Please refer to full prescribing data in the SPC or the BNF

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