SODIUM AUROTHIOMALATE (INJECTABLE GOLD) FOR USE IN RHEUMATOLOGY
Shared Care Protocol

This protocol provides prescribing and monitoring guidance for gold therapy. It should be read in conjunction with the Summary of Product Characteristics (SPC) available on www.medicines.org.uk/emc and the BNF

Shared Care Protocol – Responsibilities

Shared care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. Unless otherwise stated in the protocol, the responsibilities are as follows:

Specialist

- Initiate treatment and prescribe until the dose is stable and/or the GP formally agrees to shared care
- Ensure the patients understand the nature and complications of drug therapy and their role in reporting adverse effects promptly
- Provide copy of patient information leaflet and drug monitoring card where appropriate
- Send a letter to the GP requesting shared care. Outline shared care protocol criteria
- Liaise with GP regarding changes in disease management, drug dose, missed clinic appointments
- Be available to give advice to GP and patient throughout treatment

GP

- Prescribe medication once the dose is stable or shared care is agreed
- Ensure all monitoring is completed in accordance to the specific shared care protocol.
- Check and record results then advise the specialist of any deteriorations or abnormal results
- Notify the specialist to any changes in patients condition, any adverse drug reactions or failure to attend tests

Patient

- Agree to treatment and monitoring after making an informed decision
- Agree to being under the shared care of the GP and specialist
- Attend for blood tests and monitoring when required
- Ensure monitoring card is kept up to date and is brought to all appointments
- Report any side effects to the GP or a member of the specialist team

BACKGROUND FOR USE

Sodium aurothiomalate (Myocrisin®) is a disease modifying antirheumatic drug (DMARD) used in the treatment of:

- Rheumatoid arthritis (licensed)

This shared care protocol includes the use of gold for this indication. For all renal patients, supply of this medication will be provided in secondary care.

CONTRAINDICATIONS

- Severe hepatic or renal impairment
- History of blood disorders or marrow aplasia
- Exfoliative dermatitis
- SLE
- Necrotising enterocolitis
- Significant pulmonary fibrosis
- Porphyria
- Pregnancy and lactation
- Live vaccines

PRECAUTIONS

Mild to moderate hepatic or renal impairment.

DOSAGE

- Initial test dose of 10 mg intramuscularly (IM). It should be given in the clinic and followed by 30 minute observation for signs of allergic reaction.
- Provided there is no reaction, further doses of 50 mg, at weekly intervals, are given to a total of 1000 mg (20 weeks).
- If there has been a good therapeutic response, maintenance therapy of 50 mg at monthly intervals should be continued.
- Response is not expected until a cumulative dose of 500 mg has been given. If there is no response after a cumulative dose of 1000 mg, an alternative DMARD should be considered.
- Available as 2% and 10% IM Injections

PRE-TREATMENT ASSESSMENT BY RHEUMATOLOGIST

FBC, U&Es, LFTs, CRP and urinalysis.

ONGOING MONITORING SCHEDULE

PARAMETER	FREQUENCY AND RESULT
Urinalysis	Before each injection to check for proteinuria and haematuria. If present at greater than 1+, gold should NOT be given.
FBC	Four days after the test dose, then weekly for the first month, fortnightly for the following two months and monthly thereafter.
Enquire about skin rash and mouth ulcers	Before each injection.
Chest X-ray	If required, annually at discretion of specialist.

Note: One dose can be withheld without risk of inducing a flare
NSAIDs should be continued
Annual flu vaccinations are recommended

Please note that in addition to absolute values for haematological indices, a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance. In order to monitor trends it is recommended that all blood test results are entered in the patient held monitoring booklet.

ACTIONS TO BE TAKEN

SIDE EFFECT	ACTIONS
Anaphylactoid reactions (rare). They can occur within a few minutes after injection. Patient can complain of dizziness, nausea and vomiting, sweating and facial flushing.	Discontinue treatment and speak to a rheumatologist.
WBC $<3.5 \times 10^9$/l Neutrophils $<2.0 \times 10^9$/l	Withhold and discuss with a rheumatologist.
Platelets $<150 \times 10^9$/l	Withhold and discuss with a rheumatologist.
Proteinuria >2+	Withhold and check MSU – if evidence of infection, treat appropriately. If sterile and persistent proteinuria, withhold until discussed with a rheumatologist.
Rash (usually itchy) or oral ulceration	Withhold and speak to a rheumatologist.
Abnormal bruising or severe sore throat	Check FBC immediately and withhold until results available
Breathlessness or cough	Withhold and speak to a rheumatologist
Diarrhoea	Withhold and speak to a rheumatologist

NOTABLE DRUG INTERACTIONS

- Penicillamine: Toxicity potential increased
- ACE inhibitors: Anaphylactoid reaction possibly more common
- Increased risk of toxicity with other nephrotoxic and myelosuppressive drugs.

BACK-UP INFORMATION/ADVICE

Contact Details	Oxford University Hospitals NHS Trust	
Rheumatology	Rheumatology Helpline Rheumatology Senior Registrar on call	01865 737656 01865 741155, ask for SR on call via switchboard
Medicines Information	Tel 01865 221505	

REFRENCES

1. BNF 68, Sept 2014 to March 2015
2. Sodium Aurothiomalate SPC, EMC https://www.medicines.org.uk/emc/medicine/18616, last updated Dec 2013

Acknowledge:
Adapted from Buckinghamshire CCG Shared Care Protocols