

SHARED CARE AND NEAR PATIENT TESTING

**Drug: SODIUM AUROTHIOMALATE
(MYOCRISIN)**

Protocol number CV 19

Indication: RHEUMATOID ARTHRITIS

General Guidance

This protocol sets out details for the shared care of patients requiring sodium aurothiomalate and should be read in conjunction with the General Guidelines for Shared Care. Sharing of care requires communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **The doctor who prescribes the medication legally assumes responsibility for the drug and the consequences of its use.** The prescriber has a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should also keep up to date with the relevant guidance on the use of the medicines and on the management of the patient's condition.

Background

Sodium aurothiomalate is a slow acting drug effective in controlling disease activity in 60-70% of patients with rheumatoid arthritis. Improvement can be expected after 2-3 months (400-600 mg total dose), and in the absence of toxicity gold injections can be continued indefinitely.

Responsibilities

A. Consultant responsibilities

1. When treatment is **initiated** send Shared Care/ Near Patient Testing request form with Shared Care Protocol to GP.
2. Baseline and continued monitoring until patient is stabilised of biochemical parameters (see page 2) (If Near Patient Testing not agreed then monitoring will be continued after patient is stabilised)
3. Initiate therapy following full discussion with the patient of benefits and risks and provide monitoring booklet. Load and titrate sodium aurothiomalate dose and undertake monitoring of clinical response and side effects.
4. To counsel female patients to take contraceptive precautions during treatment. Record in GP referral letter that contraceptive advice has been given.
5. When a GP positive response to SC / NPT has been received and patient has been stabilized send a letter to GP "handing over" the Shared Care / Near Patient Testing of the patient to the GP.
6. Respond to any request from GP to review the patient due to adverse effects of therapy.
7. Advise the GP on continuing or stopping sodium aurothiomalate therapy following medical review of the patient and associated drug therapy

8. If Near Patient Testing not agreed notify GP if patient is failing to attend for appropriate monitoring and advise GP on appropriate action.

B. General practitioner responsibilities

1. Within one week of receipt return the completed Shared Care/Near Patient Testing request form to indicate whether or not willing to undertake Shared Care/Near Patient Testing.
2. Prescribe **sodium aurothiomalate** as part of the shared care agreement
3. Monitor the general health of the patient
4. Where Near Patient Testing is agreed monitor the parameters indicated (see page 2), document results in the patient's monitoring booklet and reporting to and seek advice from the consultant on any aspect of patient care which is of concern.
4. Report adverse effects of therapy to the consultant and the Medicines and Health Care products Regulatory Agency (MHRA).
5. Recommend that patient receives pneumococcal vaccination and yearly influenza vaccination as well as Zostavax as part of the national shingles immunisation programme.
6. If Near Patient Testing not agreed, to act on advice provided by the Consultant if patient does not attend for appropriate monitoring.

C. Patient responsibilities

1. Consent to treatment with sodium aurothiomalate.
2. Attend regular appointments with specialist centre and GP.
3. Report any side effects to the specialist or GP whilst receiving sodium aurothiomalate.
4. Provide monitoring booklet to be updated.

Dosage Regimen

Typical dose: 10mg intramuscular (IM) test dose (which should be given in the clinic followed by a 30 minute observation to look for signs of allergic reaction*) followed by 50mg IM weekly until there is a significant response (not expected until cumulative dose of 500mg has been given) or a total of 1000mg has been given. In patients who respond, the interval between doses may be increased by stages from 50mg per week to 50mg every 4 weeks. If there is no response after a cumulative dose of 1000mg has been given, consider alternative therapy

*Anaphylactoid or nitritoid reactions are rare but may occur just a few minutes after the injection. Dizziness, nausea, vomiting, sweating and facial flushing characterise them and necessitate discontinuation of treatment.

Monitoring

Before treatment

FBC, Creatinine and Electrolytes, LFTs, eGFR, urinalysis and skin examination.

Urine protein/creatinine ratio

Prior to each injection

FBC, urinalysis.

The patient should be asked about the presence of pruritis, rash or mouth ulcers bruising, bleeding or any other new symptom before each injection.

Provided blood results are stable the results of the FBC need not be available before the injection is given but must be available before the next injection i.e. it is permissible to work one FBC in arrears.

Urinalysis should be carried out just before each injection.

Withhold sodium aurothiomalate and discuss with specialist if any of the following occurs: -

WBC	< 4.0 x10 ⁹ /L
Neutrophils	< 1.5 x10 ⁹ /L
Platelets	< 150 x 10 ⁹ /L
Rash (usually itchy) or oral ulceration	
Abnormal bruising or severe sore throat (check FBC immediately)	

* patients may continue treatment if WBC is 3.0 - 4.0 x 10⁹ /L if the neutrophil count is above 1.5 x 10⁹ /L

If Eosinophilia > 0.5 x 10⁹/l - caution and increased vigilance required.

If proteinuria is 2+ or more - check MSSU: If evidence of infection treat appropriately. If sterile and 2+proteinuria or more persists, withhold until discussed with specialist team.

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

Adverse effects

Mucocutaneous: Pruritis, skin rashes and mouth ulcers occur in 30% of patients. Rash usually itchy, discrete, occasionally exfoliative or purpuric. It may be possible to restart at a lower dose when rash resolves but discuss with rheumatologist first.

Haematological: Rare but potentially fatal.
Reduced white cell or platelet count (see above).

- Gastrointestinal: Diarrhoea (very rare) - stop gold.
- Renal: Nephropathy (see above).
Haematuria is rare and usually occurs in association with proteinuria (procedure as above). Isolated haematuria may be secondary to NSAIDs, UTI or pathological lesions of GU tract. Also note that menstrual blood may be detected several days after period has finished.
- Others: Rarely cholestatic jaundice - stop drug. May get post-injection flare of arthritis.
Acute alveolitis.

Notable drug interactions (refer to BNF & SPC)

There are no serious drug interactions

Special Recommendations

Avoid in pregnancy and lactation.

Contact Details

If you suspect an adverse reaction has occurred please stop the drug and contact the rheumatology department at the University Hospital of Wales.

The contact numbers for the rheumatology department are 02920 742627, 02920 742626 and 02920 743184. The fax number is 02920 745017. The rheumatology nurses help line number is 02920 748191.

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