The Princess Alexandra Hospital NHS NHS Trust

NHS West Essex Clinical Commissioning Group

Shared Care Guidelines

SODIUM AUROTHIOMALATE "Gold injection"

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Key points summary

- Gold may be given by intramuscular injection as sodium aurothiomalate
- Sodium aurothiomalate must be given by deep intramuscular injection
- A test dose of sodium aurothiomalate10mg must be given followed by doses of 50mg at weekly intervals until there is definite evidence of remission, intervals are then gradually increased to 4-6 weeks
- If there is no remission after 1g of injection has been given treatment should be discontinued
- Blood monitoring is required regularly throughout treatment
- Sodium aurothiomalate is prescribable on FP10.

Introduction

Sodium aurothiomalate is the injectable form of gold. Clinical improvement is not immediate and may take 3 months to appear. A test dose of 10mg is given initially.
Subsequent doses are given at weekly intervals until there is a response or until 1 gram is reached.
The Princess Alexandra NHS Trust (PAH) and the local CCGs have agreed that Sodium aurothiomalate is suitable for shared-care.

The objectives of these guidelines are:

- To provide impartial information to GPs and community pharmacists who may not have previous experience of this drug
- To define the procedure for referral of the patient from the hospital to the GP
- To define the aspects of care for which the hospital and GP are responsible
- To define the support available from the hospital
- To establish lines of communication between GPs, Consultants and senior hospital staff

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Licensing

Sodium aurothiomalate (Myocrisin®) is used in the management of active progressive rheumatoid arthritis and progressive juvenile chronic arthritis, especially if polyarticular or seropositive.

Referral of patients

- The patient will be assessed by a rheumatology specialist, and the decision to commence gold therapy made
- For treatment with sodium aurothiomalate the test dose of 10mg and all subsequent doses must be given in an environment where appropriate medical supervision is available for 30 minutes after injection in case of anaphylaxis
- The rheumatology specialist will commence gold therapy and will provide in writing, complete treatment plan instructions.
- Any changes to dosage will be carried out in the outpatients department and transferred to GP once stable.

Initiation and maintenance of therapy

- Medication history is checked to ensure there are no contra-indications to gold therapy
- Before starting treatment and again before each injection the urine should be tested for protein (Albustix), the skin inspected for a rash and a full blood count, liver function tests and U&Es performed
- A 10mg test dose is administered intramuscularly and the patient monitored for 30 minutes in case of an anaphylactic reaction
- The first 50mg dose will be administered one week later under the same conditions
- Subsequent doses will be administered by the GP
- Subsequent doses are weekly 50mg injections of sodium aurothiomalate administered until there is a response (usually around cumulative dose of 500mgs) or until 1 gram is reached. Maintenance injections are then given fortnightly or once every four weeks according to progress

Administration/dosage

- Sodium aurothiomalate should be administered by deep intramuscular injection followed by a gentle massage of the area. The patient should remain under medical supervision for 30 minutes after administration

Injection

Adults

- An initial test dose of 10mg is given in the first week
- Weekly doses of 50mg are given until signs of remission occur
- The interval can be increased to two weeks until full remission occurs
- With full remission the interval should be increased to four and then after 18 months - 2 years to six weeks
- If no major improvement is seen after 1g has been given treatment should be stopped and alternatives considered

See SPC for more details
http://www.medicines.org.uk/emc/medicine/18613

Supply

Sodium aurothiomalate is available under the trade name Myocrisin® injection
It is manufactured by Sanofi-Aventis in the following preparations:

Sodium aurothiomalate BP 50mg in 0.5ml (10% w/v)
Sodium aurothiomalate BP 10mg in 0.5ml (2% w/v)

Prescribing

Initiation of sodium aurothiomalate injection will be made by the hospital; they will administer the test dose and the first full dose. Appropriate tests will be carried out as necessary.

Once gold treatment is considered necessary the rheumatology specialist will write to the GP detailing weekly dose to be given and review date.

Sodium aurothiomalate is prescribable on FP10.

Contra-indications

Pregnancy and lactation
Patients with gross renal or hepatic disease, a history of blood dyscrasias, exfoliative dermatitis or systemic lupus erythematosus.

Adverse effects

Severe reactions can occur in up to 5% of patients

Blood dyscrasias - sore throat, mouth ulcers, bruising, fever, malaise, rash and diarrhoea may be signs of this developing

Skin reactions - Rashes, usually benign but may be forerunners of gold toxicity
Irreversible skin pigmentation can occur in sun-exposed areas with prolonged therapy

Other - Proteinuria, rarely colitis, peripheral neuritis, pulmonary fibrosis
Hepatotoxicity with cholestatic jaundice, nephrotic syndrome, alopecia

Monitoring

Before treatment commences

- FBC, urinalysis, U&Es, ESR and LFTs

Ongoing

- Full blood count at the time of each injection.
  If previous result is not available **do not** give injection but repeat blood count and give injection once result is available and checked. (Look out for downward trends as well as absolute levels of blood cell counts.
- ESR monthly to assess response to treatment
- Urinalysis before each injection
- Patient should be asked about the presence of rash or oral ulceration before each injection

Monitoring and action

Recommendation from the British Society for Rheumatology

WBC	$<3.5 \times 10^9$/l	}	
Neutrophils	$<2.0 \times 10^9$/l	}	withhold drug and discuss
Platelets	$<150 \times 10^9$/l	}	with rheumatologist
Proteinuria	>trace}	}	
Rash/ulceration/bruising		}	

Area of responsibility for the sharing of care

Sharing of care assumes communication between the specialist, GP and the patient. The intention to share care should be explained to the patient and accepted by them

Officially the prescribing clinician has clinical responsibility for the medication they have prescribed

Responsibilities of the Consultant

- Undertake the necessary testing to confirm a diagnosis for which sodium aurothiomalate treatment is recommended
- Ensure the patient's concurrent drug therapy is stabilised and there are no contra-indications to treatment with sodium aurothiomalate
- Initiation of treatment, see initiation and maintenance of therapy
- Discussion with the patient regarding benefits and side effects of treatment
- Send a letter to the GP requesting shared care for this patient. Where shared care is being requested for the initiation to stabilisation phase, a request to share care must be made to and agreed by the GP
- To provide the patient's GP with a full summary letter indicating dose and frequency before implementation of shared care, including results of baseline tests.
- Monitoring tests as required before initial treatment
- Administration of the test dose and the first full treatment dose
- Prompt communication with the GP following an outpatient appointment of any changes in treatment (including dose adjustments) and assessments of adverse events
- Advice to GPs about all aspects of treatment
- Reporting adverse events to the CHM and GP
- http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/Informationforhealthcareprofessionals/index.htm
- Ensure clear arrangements for back-up, advice and support is available at all times
- Inform GP of patients who do not attend clinic appointments
- To provide shared care booklet/diary

Responsibilities of the General Practitioner

- To inform the Consultant in writing within 2 weeks of receipt of request to share care where the GP is NOT able to share care, otherwise the Consultant will assume shared care is agreed and expect the GP to take over monitoring and prescribing.
- To prescribe maintenance therapy to patient as advised by the specialist
- To report any adverse events to the consultant
- Prompt referral to specialist if there is any change in patient's status
- Reporting to and seeking advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment
- To monitor overall health and well-being of the patient
- Ensure compatibility with other concomitant medication
- Check their sodium aurothiomalate booklet
- To carry out blood tests and urinalysis and monitor patients as detailed in this document
- To report any adverse events to the CHM and Consultant
- http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/Informationforhealthcareprofessionals/index.htm

Responsibility of the Patient

- Report to specialist or GP if there is not a clear understanding of their treatment and discuss any concerns in relation to treatment

- Report any adverse effects to their GP and/or specialist whilst on Sodium aurothiomalate injection, especially unexplained bruising/bleeding, rashes, mouth ulcers. dyspnoea, dry cough or sore throat which should be reported immediately.
- Report any changes in disease symptoms to GP and/or specialist whilst on Sodium aurothiomalate injection.
- Inform GP or specialist of any other medicines being taken including over-the-counter products.
- Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy
- Carry and present their sodium aurothiomalate booklet to their GP, Consultant and community pharmacy at each prescribing and dispensing activity

Availability of Consultant and senior hospital staff

Rheumatology

Consultant via switchboard:	01279 444455 ext 7420
Clinical Nurse Specialist	01279 444455 ext 7434

Additional sources of advice

Pharmacy Medicines Information
The Princess Alexandra Hospital 01279 827054 (Mon-Fri 9-5)

Useful sources of information
- BNF (current edition)
- Electronic medicines compendium www.emc.medicines.org.uk/

British Society for Rheumatology 0207 2423313

Acknowledgements

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Useful information
CKS DMARDs
http://cks.nice.org.uk/dmards#!scenario:5

West Essex CCG Shared Care Webpage
Shared Care Medicines - West Essex CCG

Arthritis Research UK Patient information Letter
http://www.arthritisresearchuk.org/arthritis-information/drugs/gold-injections.aspx

GMC Prescribing Guidance: Shared Care
http://www.gmc-uk.org/mobile/news/14321