# Auranofin (oral gold) for rheumatoid arthritis and other rheumatological diseases (Adults)

It is vital for safe and appropriate patient care that there is a clear understanding of where clinical and prescribing responsibility rests between Consultants and General Practitioners (GPs).
This guideline reinforces the basic premise that:
When clinical and / or prescribing responsibility for a patient is transferred from hospital to GP, the GP should have full confidence to prescribe the necessary medicines. Therefore, it is essential that a transfer of care involving medicines that a GP would not normally be familiar with, should not take place without the "sharing of information with the individual GP and their mutual agreement to the transfer of care."
These are not rigid guidelines. On occasions, Consultants and GPs may agree to work outside of this guidance. As always, the doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

| **Indications:** | **Dosage and administration:** |
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| Auranofin (oral gold) is used in the management of active progressive rheumatoid arthritis. Auranofin was discontinued December 2009 in the UK and so no longer has a UK Marketing Authorisation. This means it is an unlicensed preparation. | Usually 3 mg twice daily with food. May be taken as single daily dose of 6 mg if well tolerated. May be increased to 9 mg daily (3mg three times a day) after 4-6 months according to clinical response.<br>If response remains inadequate after a three months trial of 9mg daily, auranofin therapy should be discontinued. |

**Additional Information**

- If anaphylactoid effects are observed, treatment should be discontinued.
- Every patient treated with auranofin (gold) should be warned to report immediately the appearance of pruritus, metallic taste, cough, sore throat or tongue, buccal ulceration or easy bruising, purpura, epistaxis, bleeding gums, menorrhagia or diarrhoea

**Monitoring requirements:**

Before treatment:

- Full blood count (FBC) including platelets, urea and electrolyes (U&Es), creatinine and liver function tests (LFTs)
- Urinalysis

During treatment:

- FBC, LFTs, U/Es, creatinine and urinalysis weekly for the first month then monthly thereafter if stable
- Patient should be asked about a rash or oral ulceration at each visit
- Annual fasting lipids (HDL, Cholesterol, HDL/Cholesterol ratio)
- ESR monthly for disease monitoring purposes

**Responsibility for monitoring rests with the GP**

**Action to be taken if abnormal results/adverse effects:**

- WBC< 3.5 x $10^9$/l Check neutrophil count
- Neutrophils < 2.0 x $10^9$/l Monitor weekly. If it falls below 1.5 x $10^9$/l STOP DRUG and contact helpline.
- Platelets < 150 x $10^9$/l Monitor weekly. If drop below 100 x $10^9$/l contact helpline

- Eosinophils >0.5 x $10^9$/l Caution and increased vigilance required
- Proteinuria 2+ or more Check MSSU: if infection present treat appropriately. If sterile and 2+ proteinuria or more persists, withhold until discussed with specialist team.
- 3 fold rise in ALT/AST Monitor weekly. If ALT continues to rise, contact helpline
- Rash Mild: drug can be continued at reduced dose if necessary.
  Severe: STOP DRUG and contact helpline
- Oral ulceration Repeat FBC and act on results as above
  Mild: salt water mouth wash
  Moderate: Hydrocortisone (Corlan®) pellets (1 applied to affected area qds)
  Severe: Hydrocortisone (Corlan®) pellets and contact helpline
- Abnormal bruising Repeat FBC and act on results as above
- Sore throat Repeat FBC and act on results as above

**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.**

**Contraindications:**

- Auranofin (gold) should not be given to women who are pregnant, or likely to become pregnant without a careful assessment of risk versus benefit.
- Breastfeeding
- Severe renal or hepatic disease
- History of blood disorders or bone marrow aplasia
- Exfoliative dermatitis
- Systemic lupus erythematosus.
- Necrotising enterocolitis
- Pulmonary fibrosis
- Acute porphyria
- Hypersensitivity to gold salts or other heavy metals
- History of or existing inflammatory bowel disease
- Live vaccines are contra-indicated in patients receiving auranofin (gold) on theoretical grounds.

**Drug interactions:**

- Concomitant therapy with metal antagonists and potentially nephrotoxic or haemotoxic drugs should be administered with caution. Such drugs include penicillamine, aminoglycosides, amphotericin B, penicillins, phenytoin, sulfonamides, NSAIDs, aciclovir and alcohol.
- Concurrent gold administration may exacerbate aspirin-induced hepatic dysfunction
- Avoid concomitant use of ACE inhibitors – increased risk of severe anaphylactoid reaction

**Cautions:**

- Elderly
- Patients with a history of allergic skin disease.
- Mild to moderate renal impairment
- Mild to moderate hepatic impairment
- Patients should be cautioned to minimise exposure to ultraviolet light

**Adverse Effects:**

Blood disorders, GI bleeding, severe anaphylactic reactions, stomatitis, taste disturbances, colitis, hepatotoxicity with cholestatic jaundice, pulmonary fibrosis, peripheral neuropathy, mouth ulcers, proteinuria, nephrotic syndrome, gold deposits in the eye, alopecia, skin reactions (rashes, pruritis and exfoliative dermatitis).

**Specialist responsibilities:**

- Confirm the diagnosis of rheumatoid arthritis
- Discuss with the patient the benefits and side effects of treatment with auranofin (oral gold)
- If the patient is a woman of child bearing potential – ensure that they are aware of the importance of effective contraception and the need to discuss with their consultant if they wish to become pregnant
- Ensure patient understands and accepts their responsibilities (see section below)
- Seek consent for treatment and document in the patient's notes.
- Ensure baseline monitoring of full blood count and biochemical profile.
- Discuss how the patient / carer can be aware of possible signs of auranofin (oral gold) toxicity or intolerance
- Provide written instruction to the GP for initiation and escalation of auranofin (oral gold).
- Provide the patient with a shared care booklet and enter the blood results into the booklet.
- Review the patient at the intervals specified below to monitor the patient's disease activity, the efficacy of the treatment and the ability to tolerate it, and consider whether continuation of treatment is appropriate.
- Discontinue if no response or patient has a significant adverse effect.
- Promptly communicate with the GP via a clinic letter any changes in treatment, results of monitoring undertaken, and assessment of adverse events. The clinic letter should clearly state if the dose has remained the same or if a dose adjustment had been made – specifically highlighting the new dose in comparison with the preceding one.
- Advise GPs when to stop treatment.
- Provide clear arrangements for back-up, advice and support.
- Report serious adverse events to the Committee on Safety of Medicines (CSM).

**GP's responsibilities:**

- Initial referral to Consultant Rheumatologist raising the possibility of rheumatoid arthritis.
- Provide the patient with monthly repeat prescriptions of medication following written instructions for initiation and escalation by the specialist. The patient should allow at least 48 hours for the prescription from the GP to be generated.
- Continue monitoring as outlined on the first page and document the results in the shared care booklet.
- Ensure patient's shared care booklet and practice computer system are updated with any dose changes.
- Refer promptly to the specialist if there is a change in the patient's status or concerns regarding compliance. In most cases, do not stop treatment without discussion with the Rheumatology Helpline.
- If patient fails to attend more than 2 monitoring visits it is not safe to continue treatment – contact the Rheumatology Helpline for advice.
- Report serious adverse events to the specialist and CSM.
- Administer Pneumococcal Vaccine/ Pneumovax® II and annual influenza vaccines
- Consider passive immunisation with Varicella zoster immunoglobulin in non-immune patients exposed to chicken pox or shingles.

**Patient responsibilities:**

- Read the written patient information provided about the drug and have a clear understanding of the risks / benefits of auranofin (oral gold) treatment.
- Attend for blood tests.
- Report any adverse effects to their GP and/or specialist whilst treated with auranofin (oral gold)
- Limit alcohol to national safe weekly limits
- Take monitoring booklet every time the patient sees the GP, has a hospital appointment or visits the pharmacist.

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| **Secondary care review:** During initiation: 4 - 6 weekly until controlled<br>**Once disease controlled:** Annual review by consultant | | |
| Availability: Unlicensed import available from Mawdsleys Specials (Ridaura brand): 3mg tabs x 30 = approximately £18.45, lead time 2 days. N.B. As this product is unlicensed it may incur additional handling fees. | | |
| **Back up advice and support:**<br>Rheumatology Helpline | | **Telephone:** 0151 604 7505 |
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