

Shared Care Guideline

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:

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.**

Dosage and administration:

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.

If response remains inadequate after a three months trial of 9mg daily, auranofin therapy should be discontinued.

Dosing in renal impairment:

CrCl 50-80ml/min: use 50% of dose

CrCl <50ml/min: avoid

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 diarrhoea, sore throat, fever, infection, non-specific illness, unexplained bleeding and bruising, purpura, mouth ulcers, metallic taste, rash, breathlessness, or cough develop.

Monitoring requirements:

Before treatment:

- Full blood count (FBC) including platelets and differential white cell count, urea and electrolytes (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 for 3 months then every 2 months thereafter if stable
- Patient should be asked about a rash and oral ulceration at each visit
- Annual fasting lipids (HDL, Cholesterol, HDL/Cholesterol ratio)
- ESR monthly (discretionary) for disease monitoring purposes

Responsibility for monitoring rests with the GP

Action to be taken if abnormal results/adverse effects:

- WBC < 3.5 x 10⁹/l Check neutrophil count
- Neutrophils < 2.0 x 10⁹/l Monitor weekly. If it falls below 1.5 x 10⁹/l STOP DRUG and contact

helpline.

- Platelets < 150 x 10⁹/l Monitor weekly. If drop below 100 x 10⁹/l contact helpline
- Eosinophils >0.5 x 10⁹/l Monitor weekly, if persistent STOP DRUG and contact helpline
- Proteinuria 1+ or more Check MSSU: if infection present treat appropriately. If sterile, repeat and if 1+ 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/pruritis 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
- Diarrhoea (very rare) STOP DRUG and contact helpline

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) with impaired immune response.

Drug interactions: see appendix 1 of current BNF before co-prescribing any drugs

- 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, pre-existing proteinuria
- Mild to moderate hepatic impairment
- Patients should be cautioned to minimise exposure to ultraviolet light
- Interstitial pneumonitis and fibrosis
- Nephrotic syndrome or glomerulitis (with proteinuria and haematuria)

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), GI disturbances and loss of appetite

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 monitoring 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 <https://yellowcard.mhra.gov.uk/>

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 monitoring 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 at <https://yellowcard.mhra.gov.uk/>
- 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.

Secondary care review: During initiation: 4 - 6 weekly until controlled

Once disease controlled: Annual review by consultant

Availability: Unlicensed import available from Mawdsleys Specials (Ridaura brand): 3mg tabs x 30 = approximately £19.48, lead time 2 days. N.B. As this product is unlicensed it may incur additional handling fees.

Please note that the price of this product varies depending on the supplier so please check the price with the patient's pharmacy.

Back up advice and support:

Rheumatology Helpline

Telephone: 0151 604 7505

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