

Hydroxychloroquine Dermatology/Rheumatology Local Safety Monitoring Schedule

Agreement to transfer of prescribing of Hydroxychloroquine to GP

Patient details

Name: _____
 Address: _____

 Date of Birth: _____
 NHS number: _____

Consultant details

Address:
 Email:
 Contact number:

GP

Address:
 Email:
 Contact number:

Agreement to be signed by GP and Consultant before prescribing is transferred to GP

Consultant Signature: _____

Date: _____

GP Signature: _____

Date: _____

This Local Safety Monitoring Schedule (LSMS) outlines suggested ways in which the prescribing responsibilities can be shared between the specialist and GP. GPs are invited to participate. If the GP feels that undertaking the roles outlined in the Schedule is outside their area of expertise or have clinical concerns about the safe management of the drug in primary care, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient's health remains with the specialist. If a specialist asks the GP to prescribe, the GP should reply to this request as soon as practicable. Sharing of care assumes communication between specialist, GP and patient.

The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Responsibilities of the specialist initiating treatment

- Discuss with the patient options for treatment and the suitability of hydroxychloroquine
- Discuss the potential benefits and side effects of treatment with the patient
- Undertake baseline tests: FBC, U&Es, and LFTs.
- Undertake an ophthalmological examination before initiating treatment. The examination should include testing visual acuity, careful ophthalmoscopy, fundoscopy, central visual field testing with a red target, and colour vision. This examination should be more frequent and adapted to the patient in the following situations: (daily dosage exceeds 6.5mg/kg lean body weight. Absolute body weight used as a guide to dosage could result in an over dosage in the obese, renal insufficiency, visual acuity below 6/8, age above 65 years and cumulative dose more than 200g).
- Repeat ophthalmological examination at least every 12 months.
- Review results of safety monitoring and request additional tests as required.
- Advise patient to stop taking hydroxychloroquine immediately and seek advice if any disturbances of vision are noted, including abnormal colour vision.
- Initiate hydroxychloroquine treatment if no abnormality detected.
- Ask the GP whether he/she is willing to participate in this Local Safety Monitoring Schedule and agree with the GP as to who will discuss this with the patient. Consultant attaches copy of Safety Monitoring Schedule from the trust intranet to printed letter.
- Titrate hydroxychloroquine to an effective dose. If both GP and Consultant feel it is appropriate, shared care may be initiated before the patient is stabilised on the effective dose, as long as the dose is stable until the next Consultant appointment.
- Or commence treatment with hydroxychloroquine and once patient is on a stable dose between visits, consider transfer of prescribing and monitoring to GP.
- Ensure agreed signed shared care form has been received back from GP to indicate that the GP is in agreement with prescribing and monitoring.

- Ensure this has been discussed with patient, and that patient has signed LSMS form
- Regular follow-up of patient (at least annually)
- Communicate promptly with the GP when treatment is changed
- Advise GP on dosage adjustment and when and how to stop treatment
- Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition and ensure that clear backup arrangements exist for GPs to obtain advice and support
- Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the General Practitioner

- Prescribe hydroxychloroquine at agreed dose.
- Refer to ophthalmologist if visual acuity changes, abnormal colour vision occurs or if vision is blurred. Warn patients to stop treatment and contact initiating specialist, if this happens.
- Request that the patient undertakes an annual visual acuity test by an optician. The patient should explain to the optician that they are taking hydroxychloroquine so that appropriate tests will be performed.
- Arrange and record on-going monitoring as agreed with specialist:
- Ensure no drug interactions with other medicines.
- Continued prescribing is appropriate for patients attending regular review
- Report adverse events to the MHRA (via Yellow Card)
- Administer influenza vaccine annually unless otherwise advised by the initiating specialist.

General Information on Hydroxychloroquine

Licensed Indication

- Rheumatoid arthritis
- Juvenile chronic arthritis
- Dermatological conditions caused or aggravated by sunlight

Dosage and administration

Adults (including the elderly)

The minimum effective dose should be employed. This dose should not exceed 6.5mg/kg/day (calculated from ideal body weight and not actual body weight) and will be either 200mg or 400mg per day.

In patients able to receive 400mg daily:

Initially 400mg daily in divided doses. The dose can be reduced to 200mg when no further improvement is evident. The maintenance dose should be increased to 400mg daily if the response lessens.

Children

The minimum effective dose should be employed and should not exceed 6.5mg/kg/day based on ideal body weight. The 200mg tablet is therefore not suitable for use in children with an ideal body weight of less than 31kg. Each dose should be taken with a meal or glass of milk.

Contraindications

- Known hypersensitivity to 4-aminoquinoline compounds
- Pre-existing maculopathy of the eye
- Pregnancy - women of childbearing potential receiving hydroxychloroquine should be advised to use effective contraception precautions. Patients discovered or planning to become pregnant should be referred to the initiating specialist at the earliest opportunity.
- Breastfeeding- women treated with hydroxychloroquine should not breastfeed

Side effects

Ophthalmic: retinopathy, corneal changes, impaired blurred vision

Skin: unexplained skin rash; pigmentary changes. May precipitate/exacerbate porphyria or psoriasis.

Gastrointestinal: nausea, diarrhoea, abdominal cramps

Blood rarely- bone marrow depression

Caution is also advised in patients with sensitivity to quinine, those with glucose-6- phosphate dehydrogenase deficiency, those with porphyria cutanea tarda which can be exacerbated by hydroxychloroquine and in patients with psoriasis as it appears to increase the risk of skin infections.

Other: cases of muscle weakness, hair loss, vertigo, tinnitus, headache, nervousness and emotional upset have been reported

Drug Interactions¹

Antacids: reduce absorption of hydroxychloroquine. Avoid administration within 4 hours of dose.

Amiodarone: increased risk of ventricular arrhythmias: avoid concomitant use.

Digoxin: possible increase in plasma concentration of digoxin.

Hypoglycaemic agents: May enhance the effect of hypoglycaemic agents

¹ BNF 66 September 2013-March 2014