



Hydroxychloroquine & Chloroquine: Amber Drug Guidance for the treatment of rheumatoid arthritis, systemic & discoid lupus erythematosus, lichen planus and obstetric indications in adults Shared Care guidance

Amber Drug Level 3 (amber drug with monitoring requirements)

Amber Level 3 'Medicines that should be initiated by a specialist, and which require significant monitoring on an ongoing basis. These medicines are considered suitable for GP prescribing (which may include titration of dose). After a successful initiation period and assessment of efficacy, a transition to GP care can take place. Full agreement to share the care of each specific patient must be reached under the amber drug agreement, and amber drug guidance must be provided to the GP (available on the West Yorkshire and Harrogate ICS site [link](#) hydroxychloroquine and chloroquine documents)

We have started your patient on hydroxychloroquine/chloroquine for either rheumatoid arthritis, systemic/discoid lupus erythematosus, lichen planus or obstetric indications. We will continue to see the patient and prescribe hydroxychloroquine/chloroquine until the patient (and their condition) is stable (minimum period of 1 month). After this period the GP will be asked to take over prescribing, titration of dose (if required) and monitoring responsibilities within this amber drug protocol.

This drug requires ongoing monitoring which does include blood tests.

This guideline outlines the specific responsibilities of the Specialist, GP, and patient when hydroxychloroquine/chloroquine is prescribed.

The link to hydroxychloroquine/chloroquine on the Leeds formulary can be found [here](#). [Link](#) to Bradford formulary, Calderdale and Huddersfield formulary [link](#), The Mid Yorkshire Hospitals Trust formulary [link](#) and Airedale Joint formulary [link](#).

Prescribing
Information

| | |
|--------------------------------|---|
| Indication for therapy: | Rheumatoid arthritis, systemic/discoid lupus erythematosus (licensed uses) or lichen planus (unlicensed use). Obstetric indications see details below. Use in obstetrics: During pregnancy & breastfeeding in women with an underlying auto-immune disorder (covered in this document) – licensed |
| Classification: | Amber Level 3 |
| Monitoring: | Required |



Baseline Tests:

- U&Es
- LFTs
- FBC
- Weight
- Check requirement for ocular monitoring in line with West Yorkshire and Harrogate Health Care Partnership [link](#) and refer if required. Inform the GP when a referral has been completed
- [policy link](#)
- [pathway link](#)
- [referral form link](#)
- [patient information leaflet link](#)

Routine Tests/Monitoring:

Renal function annually if aged over 70 and/or pre-existing renal impairment. **Calculated creatinine clearance (rather than eGFR) must be used to estimate renal function.**

A full blood count would be checked at least every 3 months during pregnancy by Secondary Care. FBC is not required in other patients or at other times.

GP to check on an annual basis whether Ocular Monitoring is due in line with West Yorkshire and Harrogate Health Care Partnership. (see above)

Please refer to the local CCGs agreed providers for ophthalmic monitoring

Disease Monitoring:

Nothing required from GP

Follow up:

Patients will usually have an annual review by their specialist.

However, patients could be discharged, from routine review, with a plan for their GP to reduce and stop therapy. If ocular monitoring has been arranged by the specialist this will be detailed in the letter. If the patient is no longer under routine specialist review they should be referred for ocular monitoring in line with the ICS APC guidance and local CCG provision.

Details about reducing and stopping hydroxychloroquine/chloroquine will be provided in the clinic letter.



The following is a summary of prescribing information only.
Consult the [BNF](#) and [SPC](#) for full and current prescribing information.

Hydroxychloroquine Dose: 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, 300mg or 400mg per day.

Chloroquine dose: (autoimmune disorders only – not used for obstetric indications): 250mg twice a day for 1-2 weeks then 250mg daily.

See clinic referral letter for recommended dose for particular patient.

The following information has been added only if it differs from the BNF and SPC or supports that information.

Pregnancy/breast-feeding: Hydroxychloroquine/chloroquine have both been used in pregnancy and are generally considered safe (British Society for Rheumatology Prescribing in Pregnancy and Breastfeeding) however it is not recommended by the manufacturer. The benefits of continuing treatments are thought to outweigh any potential harm. For more information please contact the specialist centre. The patient's treatment should not be stopped without discussion with the specialist centre.

Severe hypoglycaemia has been reported, even in the absence of anti-diabetic medication.

Contact Names and Details

Leeds Teaching Hospitals NHS Trust

Medicines Information phone number and e-mail: 0113 2064344
medicines.information@nhs.net

Medicines Information Patient Helpline phone number: 0113 2064376

Communication

Specialist who makes request via switchboard: LGI: 0113 2432799

SJUH: 0113 2433144

Areas outside of Leeds

To be included in specialist's letter

Declarations of Interest

Declarations of Interest by authors

All (or any) declarations of interest were declared and considered, through the appropriate process.

Contributors are to declare any changes to their declaration of interest submission within 28 days.



Specialist clinician responsibilities:

Responsibilities specific to hydroxychloroquine/chloroquine for the treatment of rheumatoid arthritis, systemic & discoid lupus erythematosus, lichen planus and obstetric indications in adults

- Ensure current diagnosis of condition and the treatment options have been discussed and understood by the patient and their carers where appropriate.
- Ensure that the ongoing treatment has been agreed with and by the patient and carer where appropriate.
- To assess the suitability of the patient for this treatment.
- To discuss the benefits and side effects of treatment with the patient/carer and where applicable the need for long term monitoring.
- To provide the patient with the West Yorkshire and Harrogate Health and Care Partnership information leaflet on eye monitoring ([link](#)) and discuss the information
- Checking for allergies, interactions and contra-indications.
- To perform baseline tests.
- To initiate treatment in agreement with the patient.
- To assess and monitor the patients response to treatment until stable before prescribing transferred to General Practitioner (GP).
- To ask the GP whether they are willing to take over the prescribing and monitoring responsibilities under this amber drug guidance.
- To advise the GP on dose to be prescribed and any titration schedule if appropriate.
- To advise GP what routine monitoring will be completed by the specialist and what monitoring the GP will be responsible for.
- Being explicit if for effectiveness and safety purposes the medicine should be prescribed by brand.
- To forward results of monitoring to GP.
- Outlining to the GP when therapy may be reduced and stopped assuming no relapse in patient's condition. Review periods to be agreed.
- Ensure this is also known understood and agreed with the patient (and where appropriate their carers).
- Responding to issues raised by GP and informing the patient (and carers) of any material changes to any advice shared or agreements made at the outset.
- To monitor the patient for adverse events/side effects and report to the GP and where appropriate Commission on Human Medicines/MHRA (Yellow card scheme).
- Discuss with the patient their responsibilities outlined below, confirm understanding and confirm that the patient is happy to adhere to them.

GP responsibilities:

- Checking for allergies, interactions and contra-indications when taking over prescribing and when changing treatment.
- To ensure all required monitoring is up to date before prescribing.
- To prescribe hydroxychloroquine/chloroquine and adjust the dose as recommended by the specialist following initiation and stabilisation by the specialist.
- To check that the patient has been referred for or is having ocular monitoring.
- Monitoring the patient's overall health and wellbeing, observing patient for evidence of ADRs and liaising with specialist clinician if necessary. Routine disease monitoring

*Responsibilities
of Specialist*

*Responsibilities
of GP*



should continue.

- When patient attends for review of treatment confirm, in line with the information already provided by the specialist, (or other specialist acting on their behalf) the circumstances under which the medicines should be immediately stopped and what action the patient is to take.
- To ensure that there is an agreed process in place for accessing the ongoing supply of the medicines that is not placing any unnecessary burden or workload on the patient or their carers.
- Ensuring advice is sought from the responsible specialist clinician if there is any significant change in the patient's physical health status that may affect prescribing or appropriateness of the amber medicine, or any information relevant to their care that becomes available that was not made available at the time of the specialist diagnosis and treatment option agreement.
- Reducing/stopping treatment in line with specialist clinician's original request.
- Take reasonable steps to ensure that the patient is using their medicines as prescribed and intended, i.e. include amber medication as part of medication review.
- Encourage the patient at medication review appointments to ask questions and raise any concerns they have about their treatment, particularly anything that may be affecting their adherence to treatment. Use the Me & My Medicines Charter - <https://meandmymedicines.org.uk/the-charter/>.
- To report adverse events to the specialist and where appropriate the Commission on Human Medicines/MHRA (Yellow card scheme).

Patient/carers responsibilities:

- To be responsible for taking hydroxychloroquine/chloroquine as prescribed.
- To understand how to take this medicine safely.
- To understand contents of written information provided by the Specialist and in the patient information leaflet supplied with the medicines and to seek clarification if required.
- The duration of treatment prescribed initially by the hospital specialist should be understood.
- To attend for blood tests/disease monitoring including ocular monitoring on time (as appropriate).
- To understand potential for adverse events/side effects and report these to the Specialist and/or GP.
- To understand the circumstances under which the medicines should be immediately stopped and what action to take.
- To check with the community pharmacist that there are no interactions with hydroxychloroquine/chloroquine, when buying any over the counter medicines or herbal/homoeopathic products.
- To check with dentists or other specialists who may prescribe medicines that there are no interactions with hydroxychloroquine/chloroquine.
- To contact the GP, Specialist or Medicines Information patient helpline if further information or advice is needed about this medication or if there is anything they do not understand. More information on asking about medication can be found in the Me & My Medicines Charter <https://meandmymedicines.org.uk/the-charter/>.

**Responsibilities
of Patient/Carer**