Hydroxychloroquine AMBER 0

For Treatment of rheumatoid arthritis, discoid and systemic lupus erythematosus, and dermatological conditions caused or aggravated by sunlight in adults

Information for prescribers - to be read in conjunction with the SPC

Background

Hydroxychloroquine has several pharmacological actions which may be involved in the therapeutic effect in the treatment of rheumatic disease, but the role of each is not known.

Dosage and administration

The minimum effective dose should be employed. Each dose should be taken orally with a meal or glass of milk.

Adult dose: 200–400 mg daily, daily maximum dose to be based on ideal body-weight; maximum 6.5 mg/kg per day.

The minimum effective dose should be used and will be either 200mg, 300mg or 400mg per day. If 300mg or 400mg (in divided doses) is taken initially, the dose can be reduced to 200mg when no further improvement is evident. The maintenance dose can be increased if the response lessens.

Hydroxychloroquine is cumulative in action and will require several weeks to exert its beneficial effects, whereas minor side effects may occur relatively early. For rheumatic disease treatment requires review with the specialist consultant if no improvement by 6 months. In light-sensitive diseases, treatment should only be given during periods of maximum exposure to light.

Monitoring

Patients on long-term therapy should have periodic full blood counts.

Renal function should be monitored annually in people aged over 70 years old and in those with pre-existing renal impairment, hypertension, and/or diabetes.

Retinopathy

Hydroxychloroquine sulfate should be discontinued immediately in any patient who develops a pigmentary abnormality, visual field defect, or any other abnormality not explainable by difficulty in accommodation or presence of corneal opacities.

Patients should be advised to stop taking the drug immediately and seek the advice of their prescribing doctor if any disturbances of vision are noted, including abnormal colour vision.

Annual monitoring (including fundus autofluorescence and spectral domain optical coherence tomography) is recommended in all patients who have taken hydroxychloroquine for longer than 5 years.

Annual monitoring may be started before 5 years of treatment if additional risk factors for retinotoxicity exist, such as concomitant tamoxifen therapy, impaired renal function (eGFR less than 60 mL/minute/1.73 m^2), or high-dose therapy (more than 5 mg/kg/day of hydroxychloroquine sulfate.

The specialist referring clinician should be encouraged to complete a standardised referral proforma specifying the key clinical details relevant to screening for retinal toxicity. This will allow a determination of risk toxicity and interpretation of test results (see appendix 1).

Baseline monitoring

The Royal College of Ophthalmologists have stated that baseline testing for new initiators of hydroxychloroquine or chloroquine is no longer recommended. However, the SPC for hydroxychloroquine states that patients taking hydroxychloroquine need a baseline and annual ophthalmology test. Whilst it is recommended that prescribers follow guidance from the Royal College of Ophthalmologists, they are remined that this would be an off-label use.

Version 1.4
Date: January 2026
Review: January 2029

Contraindications

- Patients with hypersensitivity to 4-aminoquinoline compounds
- Pre-existing maculopathy of the eye
- 200mg tablets in children with an ideal body weight less than 31kg

Cautions for use

MHRA/CHM advice: Hydroxychloroquine, chloroquine: increased risk of cardiovascular events when used with macrolide antibiotics; reminder of psychiatric reactions (February 2022)

Co-administration of azithromycin with hydroxychloroquine in patients with rheumatoid arthritis was associated with an increased risk of cardiovascular events (including angina or chest pain and heart failure) and mortality – see interactions section and below (psychiatric reactions) also.

Pregnancy

- Use of hydroxychloroquine in pregnancy is supported by BSR guidelines. Discussions prior to pregnancy are part of standard care. Clinicians in primary care and patients can contact specialist teams if a patient becomes pregnant while taking hydroxychloroquine.
- In case of prolonged treatment during pregnancy, hydroxychloroquine safety profile in particular ophthalmological side effects should be taken into account for child monitoring.

Retinopathy – see above

QT interval prolongation

Hydroxychloroquine has the potential to prolong the QTc interval in patients with specific risks factors. Hydroxychloroquine should be used with caution in patients with congenital or documented acquired QT prolongation and/or known risk factors for prolongation of the QT interval.

Chronic cardiac toxicity

Clinical monitoring for signs and symptoms of cardiomyopathy is advised and hydroxychloroquine sulfate should be discontinued if cardiomyopathy develops.

Suicidal behaviour and psychiatric disorders

Psychiatric side effects typically occur within the first month after the start of treatment with hydroxychloroquine and have been reported also in patients with no prior history of psychiatric disorders. Patients should be advised to seek medical advice promptly if they experience psychiatric symptoms during treatment.

Severe cutaneous adverse reactions (SCARs)

If signs and symptoms suggestive of severe skin reactions appear, hydroxychloroquine should be withdrawn at once and alternative therapy should be considered.

Hepatotoxicity

Serious cases of drug-induced liver injury (DILI) including hepatocellular injury, cholestatic liver injury, acute hepatitis, mixed hepatocellular/cholestatic liver injury and fulminant hepatic failure (including fatal cases) have been reported during use of Hydroxychloroquine.

Risk factors may include pre-existing liver disease, or predisposing conditions such as uroporphyrinogen decarboxylase deficiency or concomitant hepatotoxic medications.

Prompt clinical evaluation and measurement of liver function tests should be performed in patients who report symptoms that may indicate liver injury. Patients should be referred back to the specialist service for review and on-going management.

Excipients

Hydroxychloroquine sulfate contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

The following cautions also apply:

Extrapyramidal disorders may occur with hydroxychloroquine sulfate.

Patients presenting with clinical symptoms suggestive of hypoglycaemia during treatment with hydroxychloroquine should have their blood glucose level checked and treatment reviewed as necessary.

Patients on long-term therapy should have periodic full blood counts, and hydroxychloroquine should be discontinued if abnormalities develop.

Hydroxychloroquine sulfate should be used with caution in patients taking medicines which may cause adverse skin reactions.

Patients with a 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 since it appears to increase the risk of skin reactions.

Patients with hepatic or renal disease, and in those taking drugs known to affect those organs. Estimation of plasma hydroxychloroquine levels should be undertaken in patients with severely compromised renal or hepatic function and dosage should be adjusted accordingly.

Reactivation of hepatitis B virus has been reported in patients treated with hydroxychloroquine in combination with other immunosuppressants.

Side effects

Common or very common

Abdominal pain; appetite decreased; diarrhoea; headache; mood altered; nausea; skin reactions; vision disorders; vomiting

Uncommon

Alopecia; anxiety; corneal oedema; dizziness; eye disorders; hair colour changes; neuromuscular dysfunction; retinopathy; seizure; tinnitus; vertigo

Frequency not known

Acute hepatic failure; agranulocytosis; anaemia; angioedema; bone marrow disorders; bronchospasm; cardiac conduction disorders; cardiomyopathy; confusion; delusions; depression; hallucination; hearing loss; hypoglycaemia; leucopenia; movement disorders; muscle weakness; myopathy; photosensitivity reaction; psychiatric disorder; psychosis; QT interval prolongation; reflexes absent; severe cutaneous adverse reactions (SCARs); sleep disorder; suicidal behaviour; thrombocytopenia; tremor; ventricular hypertrophy

Drug interactions

- Carefully consider the benefits and risks before prescribing hydroxychloroquine for any patients taking azithromycin or other macrolide antibiotics, because of the potential for an increased risk of cardiovascular events and cardiovascular mortality – see MHRA alert detail (above).
- Antacids may reduce the absorption of hydroxychloroquine, a 4-hour interval is advised between hydroxychloroquine and antacids.
- As hydroxychloroquine may enhance the effects of a hypoglycaemic treatment, a decrease in doses of insulin or antidiabetic drugs may be required.
- Hydroxychloroquine can lower the convulsive threshold. Co-administration of hydroxychloroquine with other antimalarials known to lower the convulsion threshold (e.g. mefloquine) may increase the risk of convulsions. Also, the activity of antiepileptic drugs might be impaired if co-administered with hydroxychloroquine.
- Hydroxychloroquine has been reported to increase plasma ciclosporin and digoxin levels: serum digoxin levels should be closely monitored in patients receiving concomitant treatment.
- Cimetidine may increase the plasma concentration of hydroxychloroquine.
- There may be an increased risk of inducing ventricular arrhythmias if hydroxychloroquine is used concomitantly with other arrhythmogenic drugs, such as amiodarone and moxifloxacin.
- Hydroxychloroquine should be used with caution in patients receiving drugs known to prolong the QT interval, e.g., Class IA and III antiarrhythmics, tricyclic antidepressants, antipsychotics, some anti-infectives due to increased risk of ventricular arrhythmia. Halofantrine should not be administered with hydroxychloroquine.
- An increased plasma ciclosporin level was reported when ciclosporin and hydroxychloroquine were co-administered.
- Concomitant use of drugs known to induce retinal toxicity, e.g. tamoxifen and hydroxychloroquine sulfate, is not recommended.
- There is a theoretical risk of inhibition of intra-cellular α-galactosidase activity when hydroxychloroquine is co-administered with agalsidase.

This is not an exhaustive list of side effects, cautions, contra-indications or interactions please refer to the BNF or Summary of Product Characteristics for more information.

Bibliography

1. NICE Clinical Knowledge Summary (CKS). Scenario: Monitoring of DMARDs. Last revised December 2023. Accessed via: https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/ [Accessed online: 25th September 2025].
2. Summary of Product Characteristics. Hydroxychloroquine sulfate 200mg film-coated tablets. Zentiva. Accessed via: https://www.medicines.org.uk/emc/product/1764/smpc/history [Accessed online: 25th September 2025].
3. Summary of Product Characteristics. Hydroxychloroquine sulfate 300mg film-coated tablets. Blackrock Pharmaceuticals Limited. Accessed via: https://www.medicines.org.uk/emc/product/11732/smpc [Accessed online: 23rd October 2025].
4. Medicines and Healthcare Products Regulatory Agency. Drug Safety Update: Hydroxychloroquine, chloroquine: increased risk of cardiovascular events when used with macrolide antibiotics; reminder of psychiatric reactions. 15th February 2022. Accessed via: https://www.gov.uk/drug-safety-update/hydroxychloroquine-chloroquine-increased-risk-of-cardiovascular-events-when-used-with-macrolide-antibiotics-reminder-of-psychiatric-reactions#:~:text=Reminder%20of%20existing%20cardiac%20warnings,-The%20product%20information&text=Clinical%20monitoring%20for%20signs%20and,then%20treatment%20should%20be%20stopped [Accessed online: 25th September 2025].