

Annex 1: Product information updates for medicines containing hydroxychloroquine

Hydroxychloroquine products

These apply to all authorised medicines in the UK that include hydroxychloroquine.

SPC section 4.4

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 section 4.5).

SPC section 4.5 (under an appropriate subheading if section 4.5 includes subheadings based on the interacting medicines or the type of interaction)

Observational data have shown that co-administration of hydroxychloroquine with azithromycin in patients with rheumatoid arthritis is associated with an increased risk of cardiovascular events and cardiovascular mortality. Carefully consider the balance of benefits and risks before prescribing hydroxychloroquine for any patients taking azithromycin. Similar careful consideration of the balance of benefits and risks should also be undertaken before prescribing hydroxychloroquine for any patients taking other macrolide antibiotics, such as clarithromycin or erythromycin, because of the potential for a similar risk when hydroxychloroquine is co-administered with these medicines.

Patient Information Leaflet

Section 2. What you need to know before you take <product name/INN> (to be included as a bullet point under the appropriate subheading, e.g. “Taking other medicines”, “Other medicines and <product name/INN>”, etc.)

- Some antibiotics used for infections (such as azithromycin, clarithromycin, erythromycin, gentamicin, neomycin or tobramycin). Taking azithromycin, clarithromycin, or erythromycin at the same time as hydroxychloroquine may increase the chance of you getting side effects that affect your heart.