

Annex 3: Product information updates for medicines containing azithromycin

Azithromycin products

These apply to all authorised medicines in the UK that include azithromycin administered systemically (oral or intravenous use).

SPC section 4.4

Carefully consider the balance of benefits and risks before prescribing azithromycin for any patients taking hydroxychloroquine or chloroquine, 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 azithromycin with hydroxychloroquine 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 azithromycin for any patients taking hydroxychloroquine. Similar careful consideration of the balance of benefits and risk should also be undertaken before prescribing azithromycin for any patients taking chloroquine, because of the potential for a similar risk with chloroquine.

Patient Information Leaflet

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

- Hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria): Taking these medicines at the same time as azithromycin may increase the chance of you getting side effects that affect your heart.