

## **Annex 2: Product information updates for medicines containing chloroquine**

### **Chloroquine products**

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

#### **SPC section 4.4**

Carefully consider the benefits and risks before prescribing chloroquine for any patients taking 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. Because similar risks may potentially be present with chloroquine, careful consideration should be given to the balance of benefits and risks before prescribing chloroquine for any patients taking azithromycin or other macrolide antibiotics, such as clarithromycin or erythromycin.

### **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.)**

- Azithromycin, clarithromycin, or erythromycin (antibiotics used for treating infections). Taking these medicines at the same time as chloroquine may increase the chance of you getting side effects that affect your heart.