

A Target Product Profile for primaquine

A target product profile was developed by the group (see below) in order to support the planning of necessary trials.

- Indications and usage – Transmission blocking agent for co-administration with ACTs.
- Safety – Maximum safety because no immediate benefit to individual, ideally safe in pregnancy. The acceptable serious adverse effect rate is to be weighed against the number of cases/ malaria morbidity events averted and the risks associated with prophylaxis. The benefits to the individual should be considered as potential prevention of re-infection when primaquine is appropriately deployed. There should be no adverse interactions with antiretroviral or anti-tuberculosis therapy.
- Efficacy/Endpoint: High efficacy for blocking transmission to mosquitoes at day 7 and reducing day 7 gametocyte carriage.
- Dosing regimen: co-administered with ACT. Primaquine given on either day 1, or day 3. Simple oral dosing (available small-dose formulations), paediatric formulation.
- Cost: <\$1.
- Co-packaging or co-formulation with ACT preferred.
- Exclude from indication:
 - Ideally no one.
 - Fall back: G6PD deficient (including a pregnant women if she or the father of the baby has G6PD deficiency). If there are exclusions, the added operational considerations (G6PD deficiency test performance and cost, logistics and risks in pregnancy) required to carry out the additional screening will need to be evaluated.