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Tafenoquine receives regulatory approval in USA for prophylaxis of malaria and radical cure of *Plasmodium vivax*

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Tafenoquine has been approved by the United States Food and Drug Administration (FDA) for prophylaxis of malaria in adults (Arakoda™, 60 Degrees Pharmaceutical, 100 mg tablets) and for radical cure of *Plasmodium vivax* in persons greater than 16 years old (Krintafel™, GSK, 150 mg tablets).[1,2] Tafenoquine is only the second drug of its kind to receive regulatory approval. An 8-aminoquinoline drug related to primaquine, tafenoquine, effectively kills the dormant liver stage of the *P. vivax* parasite responsible for relapses of malaria, and, like primaquine, should not be used in those with glucose-6-phosphate dehydrogenase (G6PD) deficiency. These regulatory approvals add not only another option for the prevention and treatment of malaria in travellers but also a powerful tool for malaria control and elimination globally.

Tafenoquine's long half-life of approximately 2 weeks allows for fewer doses. When used for malaria prophylaxis, a 200-mg dose of tafenoquine is taken daily for 3 days prior to travel, weekly during travel and once after returning.[2] The use of tafenoquine for preventing malaria in travellers addresses two main challenges with malaria prophylaxis. First, poor adherence may be improved with the weekly dosing schedule, and the shorter course afforded by its causal prophylactic activity.[3] The dosing regimen may be appealing for those with shorter trips or seeking last-minute travel advice. Second, with the exception of primaquine used off-label, none of the currently used antimalarials for prophylaxis has anti-hypnozoiticidal activity against the dormant liver stages of vivax that could cause malaria months after travel. Tafenoquine has anti-hypnozoiticidal activity, and similar prophylactic outcomes as mefloquine.[4]

For persons with uncomplicated *P. vivax* malaria, an oral antimalarial is given for treatment of the blood stage of the parasite present during acute infection and an additional medication is given to kill the dormant liver stages that cause relapse (radical cure). Previously, the only drug available for radical cure was primaquine taken for 14 days, but tafenoquine has a

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similar efficacy with a single 300 mg dose.[5] As efficacy is partly influenced by adherence, tafenoquine's single-dose regimen is its main advantage.

The primary safety concern with tafenoquine is the same as that for primaquine: severe haemolytic anaemia can occur in those with G6PD deficiency.[1,2] If the G6PD status is unknown, quantitative and not just qualitative G6PD testing must be done prior to tafenoquine administration. Also, since a foetus would have an unknown G6PD status, tafenoquine should not be used in pregnant women or in lactating mothers with infants of deficient or unknown G6PD status. Tafenoquine at prophylaxis doses is not recommended in those with psychotic disorders. The most common adverse reactions observed at both prophylaxis and treatment doses include dizziness, nausea, vomiting, headache, and non-clinically significant decreases in haemoglobin.[1,2] Tafenoquine should be administered with food.

This approval by the US FDA is the first step to making tafenoquine available for use against malaria worldwide. Future review by regulatory authorities in other countries will potentially allow malaria control programs in endemic countries to consider its use in strategies for malaria elimination.

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