



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 July 2015  
EMA/CHMP/464758/2015  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup>

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### Mosquirix

#### *Plasmodium falciparum* and hepatitis B vaccine (recombinant, adjuvanted)

On 23 July 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in accordance with Article 58 of Regulation (EC) No 726/2004 for the medicinal product Mosquirix, intended for active immunisation against malaria in young children (see full indication below). The applicant for this medicinal product is GlaxoSmithKline Biologicals S.A.

Mosquirix will be available as a 25-µg powder and solvent for suspension for injection in vials. The active substance of Mosquirix is *Plasmodium falciparum* circumsporozoite protein fused with hepatitis B surface antigen, and combined with hepatitis B surface antigen(s) in the form of non-infectious virus-like particles produced in yeast cells (*Saccharomyces cerevisiae*) by recombinant DNA technology. Mosquirix is a pre-erythrocytic vaccine that limits the ability of *P. falciparum* to infect, mature and multiply in the liver by eliciting humoral and cellular immunity to the circumsporozoite protein. In addition, Mosquirix induces protection against hepatitis B by eliciting humoral responses.

The benefits with Mosquirix are its ability to provide protection against malaria in infants and children aged from 6 weeks to 17 months. In infants aged 6 to 12 weeks the vaccine's efficacy against the first or only episode of clinical malaria over 12 months of follow-up was 31%, while in children aged 5 to 17 months it was 56%. During a follow-up period of over 36 months, the vaccine's efficacy against all episodes of malaria was 27% in infants aged 6 to 12 weeks, and 46% in children aged 5 to 17 months.

The most common side effects are fever, injection site reactions and irritability.

The full indication is: "Mosquirix is indicated for active immunisation of children aged 6 weeks up to 17 months against malaria caused by *Plasmodium falciparum* and against hepatitis B (see sections 4.2, 4.4 and 5.1).

The use of Mosquirix should be based on official recommendations considering *Plasmodium falciparum* malaria epidemiology in different geographical areas".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR).

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<sup>1</sup> Scientific opinion in accordance with Article 58 of (EC) No Regulation 726/2004 in the context of cooperation with the World Health Organisation (WHO)



This medicinal product is exclusively intended for markets outside the European Union.