



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2025
EMA/CHMP/109053/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion (post authorisation)

Mosquirix

Plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted)

On 27 March 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in accordance with Article 58 of Regulation (EC) No 726/2004¹, recommending a change to the product information for the medicinal product Mosquirix. The change for this medicinal product has been requested by GlaxoSmithKline Biologicals S.A.

The CHMP adopted an addition to the indication to clarify that children should be between 6 weeks and 17 months old at the time of the first dose of Mosquirix. The indication for Mosquirix will therefore be as follows:²

Mosquirix is indicated for active immunisation of children aged 6 weeks up to 17 months **(at the time of the first dose)** 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.

In addition, the CHMP adopted an amendment to the posology to support the flexibility in administration of a fourth dose at 12- or 18-months post-Dose 3 and to recommend annual revaccination until 5 years of age. The posology section for Mosquirix will therefore be as follows:³

Vaccination in children from 6 weeks up to 17 months of age (at first dose):

- Three doses, each of 0.5 mL, should be given at monthly intervals.
- A fourth dose is recommended **from 12 to** 18 months after the third dose.

- After the fourth dose, annual revaccination until 5 years of age may be considered (see section 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of

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

² New text in bold

³ New text in bold



product characteristics (SmPC), which will be published on the EMA website.

Mosquirix is intended exclusively for markets outside the European Union.