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EPAR summary for the public

Mosquirix

plasmodium falciparum and hepatitis B vaccine (recombinant, adjuvanted)

This is a summary of the European public assessment report (EPAR) for Mosquirix. It explains how the Agency assessed the medicine to recommend its approval and its conditions of use. It is not intended to provide practical advice on how to use Mosquirix.

For practical information about using Mosquirix, patients should read the package leaflet or contact their doctor or pharmacist.

What is Mosquirix and what is it used for?

Mosquirix is a vaccine that is given to children aged 6 weeks to 17 months to help protect against malaria caused by the parasite *Plasmodium falciparum*.

The vaccine should only be used in areas of the world where malaria caused by *Plasmodium falciparum* is prevalent, and according to official recommendations in those areas.

Mosquirix also helps protect against infection of the liver with the hepatitis B virus but should not be used only for this purpose.

How is Mosquirix used?

Mosquirix is given as a 0.5 ml injection into a muscle of the thigh or in the muscle around the shoulder (the deltoid). The child is given three injections with one month between each injection. A fourth injection is recommended 18 months after the third.

The medicine can only be obtained with a prescription.

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How does Mosquirix work?

The active substance in Mosquirix is made up of proteins found on the surface of the *Plasmodium falciparum* parasites and the hepatitis B virus.

When a child is given the vaccine, the immune system recognises the proteins from the parasite and virus as 'foreign' and makes antibodies against them. The immune system will then be able to produce antibodies more quickly when the child is naturally exposed to the malaria parasites and the hepatitis B virus in the future.

Mosquirix induces antibodies against malaria parasites that have entered the blood (via a mosquito bite) and have reached or are traveling to the liver, where they can mature and multiply. The vaccine thus limits the ability of the parasites to mature in the liver and cause clinical disease.

What benefits of Mosquirix have been shown in studies?

Mosquirix is effective at reducing the number of children who have *Plasmodium falciparum* malaria in the 12 months following the third injection. In a study involving over 12,000 children in 7 African countries, the number of children who had malaria in a 12 month period was lower by 24% among children aged 6 to 12 weeks (at first dose) who were given Mosquirix and by 43% in children given the first dose between the age of 5 to 17 months.

Mosquirix was also shown to induce antibodies against the hepatitis B virus as least as effectively as a currently authorised hepatitis B vaccine.

What are the risks associated with Mosquirix?

The most serious side effect reported in clinical studies with Mosquirix was febrile seizures (fits with fever), which occurred in 1 child in 1,000. The most common side effects were fever (in about 1 child in 4), irritability and injection site reactions such as pain (in around 3 children in 20) and swelling (in less than 1 in 10).

Mosquirix must not be used in children who have had a hypersensitivity (allergic) reaction to a previous dose of Mosquirix or to a hepatitis B vaccine.

For the full list of restrictions, see the package leaflet.

Why is Mosquirix approved?

Mosquirix provides short-term protection that could potentially save lives in the age group most at risk from malaria. The main study of Mosquirix showed that the vaccine can prevent malaria in children aged 6 weeks to 17 months at the time of the first dose. The protection afforded by the vaccine reduced over time after three doses and, for this reason, a fourth injection is recommended 18 months after the first three injections.

With regard to its risk, the safety of Mosquirix is similar to that of other vaccines. A small number of children may have seizures caused by high fever and can be managed with fever medication in accordance to local guidelines.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that the benefits of the vaccine outweigh its risks and issued a positive scientific opinion.

What measures are being taken to ensure the safe and effective use of Mosquirix?

A risk management plan has been developed to ensure that Mosquirix is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Mosquirix, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Mosquirix

The CHMP gave a positive scientific opinion on Mosquirix on 23 July 2015. This opinion was given as part of the EMA's cooperation with the World Health Organisation, whereby the CHMP provides opinions on medicines that are not intended for use in the EU but are needed to prevent or treat diseases of major public health importance around the world.

The full EPAR and risk management plan summary for Mosquirix can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Medicines for use outside the EU. For more information about treatment with Mosquirix, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2015.