23 June 2011
EMA/CHMP/207988/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Eurartesim

dihydroartemisinin/piperaquine phosphate

On 23 June 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Eurartesim, 20 mg / 160 mg, 40 mg / 320 mg, Film-coated tablet, intended for the treatment of uncomplicated *Plasmodium falciparum* malaria in adults, children and infants 6 months and over and weighing 5 kg or more. Eurartesim was designated as an orphan medicinal product on 3 August 2007. The applicant for this medicinal product is Sigma-tau Industrie Farmaceutiche Riunite S.p.A. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Eurartesim is dihydroartemisinin / piperaquine phosphate, a fixed combination of a known blood schizontocide and an aminoquinoline (ATC Code: P01BF05). Dihydroartemisinin reaches high concentrations within the parasitized erythrocytes. Its endoperoxide bridge is thought to be essential for its antimalarial activity, causing free-radical damage to parasite membrane systems. The exact mechanism of action of piperaquine is however unknown, but it likely mirrors that of chloroquine, a close structural analogue. Its bulky bisquinolone structure may be important for activity against chloroquine- resistant strains, and may act through the following mechanisms: inhibition of the transporters that efflux chloroquine from the parasite food vacuole and inhibition of haem-digestion pathway in the parasite food vacuole.

The benefits with Eurartesim are its potential to be active against *Plasmodium falciparum* worldwide. As shown in the two pivotal studies conducted in Asia (including areas with multiple drug resistant falciparum strains) and in Africa, Eurartesim proved non-inferior to established standard-of-care comparator drugs. The most common side effects observed were anaemia, headache, asthenia and QTc prolongation.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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A pharmacovigilance plan for Eurartesim will be implemented as part of the marketing authorisation.

The approved indication is: “Eurartesim is indicated for the treatment of uncomplicated *Plasmodium falciparum* malaria in adults, children and infants 6 months and over and weighing 5 kg or more.

Consideration should be given to official guidance on the appropriate use of antimalarial agents.”

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), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Eurartesim and therefore recommends the granting of the marketing authorisation.