EMA/526898/2016
EMEA/H/C/001199

EPAR summary for the public

Eurartesim

piperaquine tetraphosphate / artenimol

This is a summary of the European public assessment report (EPAR) for Eurartesim. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Eurartesim.

What is Eurartesim?

Eurartesim is a malaria medicine that contains the active substances piperaquine tetraphosphate and artenimol. It is available as tablets (160 mg/20 mg; 320 mg/40 mg).

What is Eurartesim used for?

Eurartesim is used to treat uncomplicated malaria caused by the *Plasmodium falciparum* parasite. 'Uncomplicated' means the disease does not involve severe, life-threatening symptoms. It can be used in adults and children aged 6 months and over and weighing 5 kg or more.

The medicine can only be obtained with a prescription.

How is Eurartesim used?

Eurartesim is taken once a day for three consecutive days, at the same time each day. The dose is determined by the patient's body weight. The tablets are swallowed with water when the stomach is empty, at least three hours before or after a meal. The tablets may be crushed and mixed with water if needed. For more information, see the package leaflet.

How does Eurartesim work?

Malaria is an infection caused by a parasite known as Plasmodium and spread through the bite of an infected mosquito. The active substances in Eurartesim, piperaquine tetraphosphate and artenimol, are antimalarial substances which kill the *P. falciparum* parasite. Piperaquine tetraphosphate is a so-called

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bisquinolone. It is chemically related to other widely available medicines used to treat malaria. It is thought to work by blocking a step in the parasite's metabolism needed for its survival. Artenimol is a derivative of the naturally occurring substance artemisinin. Although the exact way in which it kills the parasite is not fully understood, it is believed to damage the parasite membrane.

How has Eurartesim been studied?

Eurartesim was investigated in two main studies in patients with uncomplicated *P. falciparum* malaria. In the first study, Eurartesim was compared with another malaria medicine containing artesunate and mefloquine in 1,150 patients. The main measure of effectiveness was the proportion of patients who were cured 63 days after treatment. In the second study, Eurartesim was compared with another medicine containing artemether and lumefantrine in 1,553 children. The main measure of effectiveness was the proportion of patients who were cured 28 days after treatment.

What benefit has Eurartesim shown during the studies?

Eurartesim was shown to be effective in treating uncomplicated *P. falciparum* malaria. In the first study, 63 days after treatment 97% of patients who received Eurartesim had been cured, compared with 95% of patients treated with the comparator medicine. In the second study, 28 days after treatment 93% of patients who received Eurartesim had been cured, compared with 95% of patients treated with the comparator medicine.

What is the risk associated with Eurartesim?

In adults, the most common side effects with Eurartesim (seen in between 1 and 10 patients in 100) are anaemia (low red blood cell counts), headache, QTc interval prolongation (an alteration of the electrical activity of the heart, which can cause a life-threatening abnormality of heart rhythm), tachycardia (rapid heartbeat), weakness, and fever. In children, the most common side effects with Eurartesim (seen in more than 1 patient in 10) were influenza (flu), cough and fever. For the full list of all side effects with Eurartesim, see the package leaflet.

Eurartesim must not be used in patients with severe malaria. It must not be used in patients who have or are at risk of QTc interval prolongation or cardiac arrhythmias (unstable heart rhythm) or who are taking medicines that can affect heart rhythm. For the full list of restrictions, see the package leaflet.

Why has Eurartesim been approved?

The CHMP considered that Eurartesim had been shown to be effective in treating uncomplicated *P. falciparum* malaria while the side effects were similar to those seen with comparable treatments. The CHMP noted the potential risk for QTc interval prolongation, and included restrictions in the product information to minimise the risk to patients. The Committee noted that Eurartesim meets World Health Organization recommendations for *P. falciparum* malaria treatment by offering a new alternative artemisinin combination therapy containing two active substances which work in different ways. Therefore, the Committee concluded that the benefits of Eurartesim outweigh its risks and recommended that it be granted marketing authorisation.

What measures are being taken to ensure the safe use of Eurartesim?

The company that markets Eurartesim will provide all doctors expected to prescribe or use Eurartesim with an educational pack containing important information on the correct use of the medicine, including

a checklist of the medicines that Eurartesim must not be given with, to reduce the risk of QTc interval prolongation. The Eurartesim carton is to include instructions to take the medicine at least 3 hours before or after food. The company will also complete a study on Eurartesim's effects on the heart.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Eurartesim have also been included in the summary of product characteristics and the package leaflet.

Other information about Eurartesim

The European Commission granted a marketing authorisation valid throughout the European Union for Eurartesim on 27 October 2011.

The full EPAR for Eurartesim can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Eurartesim, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2016.