



19 November 2015
EMA/CHMP/719685/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹

Pyramax

pyronaridine-artesunate

On 19 November 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, recommending a change to the terms of the scientific opinion for the medicinal product Pyramax. The applicant for this medicinal product is Shin Poong Pharmaceutical Co., Ltd.

For the currently available 180 mg/60 mg film-coated tablets, the CHMP adopted a change to the existing indication as follows²:

“Pyramax tablets are indicated in the treatment of acute, uncomplicated malaria infection caused by *Plasmodium falciparum* or by *Plasmodium vivax* in adults and children weighing 20 kg or more, ~~in areas of low transmission with evidence of artemisinin resistance.~~

~~Pyramax is to be used only as a single treatment course in any given patient (see section 4.2 and 4.4.).~~

Consideration should be given to official guidance on the appropriate use of antimalarial agents (see section 4.4).”

In addition, the CHMP recommended extending the scientific opinion for Pyramax to include one new presentation: granules for oral suspension (containing 60 mg pyronaridine tetraphosphate and 20 mg artesunate). The granules are for use in children and infants weighing 5 kg to under 20 kg.

For the granules, the CHMP adopted an indication as follows:

“Pyramax granules for oral suspension are indicated in the treatment of acute, uncomplicated malaria infection caused by *Plasmodium falciparum* or by *Plasmodium vivax* in children and infants weighing 5 kg to under 20 kg.

Consideration should be given to official guidance on the appropriate use of antimalarial agents (see section 4.4).”

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 Removed text as strikethrough.



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).

Pyramax is exclusively intended for markets outside the European Union.