16 September 2021
EMA/CHMP/438991/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Artesunate Amivas

artesunate

On 16 September 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Artesunate Amivas[2], intended for initial treatment of severe malaria in adults and children.

The applicant for this medicinal product is Amivas Ireland Ltd.

Artesunate Amivas will be available as 110 mg powder and solvent for solution for injection. The active substance of Artesunate Amivas is artesunate, an antiprotozoal (ATC code: P01BE03) which is expected to generate an unstable organic free radical followed by alkylation. The free radical binds to malarial proteins, triggering the destruction of parasite membranes.

The main benefit of Artesunate Amivas is improved in-hospital survival for patients suffering severe malaria. The most common side effects consist of delayed post-treatment red blood cell lysis (breakdown), anaemia, and reduced reticulocyte count.

The full indication is:

> Artesunate Amivas is indicated for the initial treatment of severe malaria in adults and children (see sections 4.2 and 5.1).
>
> Consideration should be given to official guidance on the appropriate use of antimalarial agents.

Artesunate Amivas should be used to treat patients with severe malaria only after consultation with a physician with appropriate experience in the management of malaria.

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 made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[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
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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