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Artesunate Amivas (*artesunate*)

An overview of Artesunate Amivas and why it is authorised in the EU

What is Artesunate Amivas and what is it used for?

Artesunate Amivas is a malaria medicine used as initial treatment of severe malaria in adults and children. Malaria is an infection caused by a parasite known as Plasmodium. 'Severe' malaria means the disease involves potentially life-threatening symptoms.

Malaria is rare in the EU, and Artesunate Amivas was designated an 'orphan medicine' (a medicine used in rare diseases) on 28 February 2020. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3202251.

Artesunate Amivas contains the active substance artesunate.

How is Artesunate Amivas used?

Artesunate Amivas can only be obtained with a prescription, and prescribers should take into account official guidance on the use of antimalarial agents. The medicine should only be used after consultation with a doctor experienced in the management of malaria.

The medicine is available as a powder and solvent to be made up into a solution for injection into a vein. The recommended dose is based on the patient's weight and should be given every 12 hours during the first 24 hours (0, 12 and 24 hours). Treatment with Artesunate Amivas should continue with one injection every 24 hours until the patient is able to take appropriate malaria treatment by mouth.

For more information about using Artesunate Amivas, see the package leaflet or contact your doctor or pharmacist.

How does Artesunate Amivas work?

The active substance in Artesunate Amivas, artesunate, is a derivative of the naturally occurring substance artemisinin. Its exact mode of action is not fully understood, but once it has entered blood cells infected by the malaria parasite, the medicine is thought to form toxic substances called 'free radicals' that kill the parasite.

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What benefits of Artesunate Amivas have been shown in studies?

Two main studies showed that initial treatment with injectable artesunate was more effective than that with another malaria medicine, quinine, in reducing the risk of death in hospitalised patients with severe malaria.

The first study involved 1,461 adults and children. Patients received injectable treatment until they were able to receive treatment by mouth, either with Artesunate Amivas or with quinine. The results showed that 107 out of 730 (14.7%) patients who received initial treatment with Artesunate Amivas died in hospital compared with 164 out of 731 (22.4%) of those who received initial treatment with quinine.

In the second study, which involved 5,425 children under 15 years of age hospitalised with malaria, 230 out of 2712 (8.5%) patients who received Artesunate Amivas by injection followed by treatment with the malaria medicine artemether-lumefantrine died in hospital compared with 297 out of 2713 (10.9%) of those who received quinine by injection followed by artemether-lumefantrine.

What are the risks associated with Artesunate Amivas?

The most common side effects with Artesunate Amivas (which may affect more than 1 in 10 people) are anaemia (low levels of red blood cells), reticulocytopenia (low levels of reticulocytes, a type of immature red blood cell) and post-artesunate delayed haemolysis (breakdown of red blood cells at least seven days after starting artesunate treatment, which may cause anaemia).

For the full list of side effects and restrictions of Artesunate Amivas, see the package leaflet.

Why is Artesunate Amivas authorised in the EU?

Two studies have shown that initial treatment with Artesunate Amivas given by injection improves in-hospital survival in adults and children with severe malaria compared with quinine given by injection. The safety profile of Artesunate Amivas when given by injection into a vein was considered acceptable. The European Medicines Agency therefore decided that Artesunate Amivas's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Artesunate Amivas are continuously monitored. Suspected side effects reported with Artesunate Amivas are carefully evaluated and any necessary action taken to protect patients.

Other information about Artesunate Amivas

Artesunate Amivas received a marketing authorisation valid throughout the EU on 22 November 2021.

Further information on Artesunate Amivas can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/artesunate-amivas/

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