

artesunate - New orphan drug approval

- On May 26, 2020, the <u>FDA announced</u> the approval of Amivas' <u>artesunate</u>, for the initial treatment of severe malaria in adult and pediatric patients. Treatment of severe malaria with artesunate should always be followed by a complete treatment course of an appropriate oral antimalarial regimen.
 - Artesunate does not treat the hypnozoite liver stage forms of *Plasmodium* and will therefore not prevent relapses of malaria due to *Plasmodium vivax* or *Plasmodium ovale*.
 - Concomitant therapy with an antimalarial agent such as an 8-aminoquinoline drug is necessary for the treatment of severe malaria due to *P. vivax* or *P. ovale*.
- According to the CDC, approximately 2,000 cases of malaria are diagnosed in the U.S. each year, with 300 of those infected having severe disease.
- Artesunate is rapidly metabolized into an active metabolite dihydroartemisinin (DHA). Both artesunate
 and DHA are active against the different asexual forms of the *Plasmodium* parasites and clear
 parasitemia within 48 to 72 hours.
- The efficacy of artesunate for the treatment of malaria was supported by a randomized, active-controlled, open-label study in Asia and a published, randomized, active-controlled, open-label study in Africa. The first study included 1,461 patients hospitalized with severe malaria and treated with artesunate or quinine.
 The second study included pediatric patients < 15 years of age and treated with artesunate or quinine.
 - In the first study, the in-hospital mortality rate in the artesunate group was significantly lower than the rate in the quinine group (13% vs. 21%, respectively; odds ratio: 0.59; 95% CI: 0.44, 0.79).
 - In the second study, treatment with artesunate compared to quinine, showed a similar advantage with respect to in-hospital mortality as in the first study.
- Warnings and precautions of artesunate include post-treatment hemolysis, hypersensitivity, and embryofetal toxicity in animals.
- The most common adverse effects (≥ 2%) with artesunate use were acute renal failure requiring dialysis, hemoglobinuria, and jaundice.
- The recommended dose of artesunate is 2.4 mg/kg administered intravenously at 0 hours, 12 hours, and 24 hours, and thereafter, administered once daily until the patient is able to tolerate oral antimalarial therapy.
 - Artesunate should be administered with an antimalarial agent that is active against the hypnozoite liver stage forms of *Plasmodium*, such as an 8-aminoquinoline drug, to patients with severe malaria due to *P. vivax* or *P. ovale*.
- Amivas' launch plans for artesunate are pending. Artesunate will be available as an 110 mg powder for reconstitution.



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