

INFORMATION FOR HEALTHCARE PROFESSIONAL

Unexpected Adverse Following The Administration of Artesunate Injection on Five Patients in Manokwari District, West Papua

Artesunate is one of the antimalarial drugs of Artemisinin derivatives. In Indonesia, Artesunate is available in tablet and injection dosage forms. Artesunate injection drugs are approved for use in the treatment of severe malaria including malaria caused by *P. Falciparum*, which is resistant to chloroquine.

In May 2016 there were Unexpected Adverse Event (UAE) after administration of the Artesunate Injection anti-malarial drug in 5 (five) patients at almost the same time in one health service facility in Manokwari District, West Papua. The five patients did not experience severe malaria but were given Artesunate injections anti-malarial drug with the appropriate dose for severe malaria. UAE that occurred were almost similar (fever, severe chills, vomiting, heart palpitations, weakness, dizziness, and reaction appeared about 1 hour after the injection of Artesunate) except for one patient aged 13 years old, the UAE was with a seizure. UAE occurred after second or third Artesunate injection. After the administration of Artesunate injection was stopped, the patient's condition gradually showed improvement (*recovered*).

NADFC together with Adverse Drug Reaction Events Advisory Committee and the Malaria Sub Directorate has conducted an assessment meeting for the UE case that occurred. Based on the results of the discussion conducted, it was concluded that 5 cases that occurred were related to the use of Artesunate injection. In addition to the five cases of the UE, NADFC as the National MESO/Pharmacovigilance Center has not received any reports of similar UE cases on the use of Artesunate Injection.

Based on the Artesunate injection product information, complaints of nausea side effects, headache, fever, seizures have been listed, but the side effects of palpitations have not been listed. From the literature search results, WHO - Essential Medicines and Health Product Information and Medscape mentioned some of the ESOs that can occur in the use of Artesunate injection drugs such as fever, rash, cardiotoxicity (high dose), and neurotoxicity (observed in animal experimental studies).

NADFC conveys this information to health professionals to increase caution in the administration of the Artesunate injection drug primarily in patients with cardiovascular risk factors (such as hypertension, hypercholesterolemia, diabetes, etc.) and calls for professional health professionals to report ESO using the MESO Yellow Form or to report online to NADFC through the sub-site <http://e-meso.pom.go.id> so that with sufficient data, the safety of products circulating in Indonesia can be evaluated and drug information can be given to patients based on the population data in Indonesia.

NADFC will continuously monitor the aspect of drug safety in order to provide optimal protection to the public health, and as an effort to ensure the drug safety in Indonesia.