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INFORMATI ON FOR HEALTHCARE PROFESSIONAL

Peginterferon Alfa - 2a and the Risk of Facial Palsy

Peginterferon Alfa-2a is a drug indicated for the treatment of HBeAg positive and HBeAg negative chronic hepatitis B in patients with non-cirrhosis and cirrhosis with liver disease and evidence of viral replication, elevated ALT and histology verified by inflammation of the liver and/or fibrosis. Peginterferon Alfa-2a is also indicated for the treatment of chronic hepatitis C in adult patients with positive HCV-RNA serum. In hepatitis C treatment, Peginterferon Alfa-2a is combined with ribavirin for optimal results.

In December 2015, Therapeutic Goods Administration (TGA) -Australia informed about the risk of facial palsy on the use of Peginterferon Alfa-2a. Until August 19, 2015, the TGA has received five reports of VII paralysis associated with Peginterferon Alfa-2a, including three cases in which Peginterferon Alfa-2a was the only suspected drug. Based on TGA post marketing adverse drug reaction autority in Australia and in the world, it is identified that there is a potential risk of neurological palsy VII (also known as Bell palsy) on the use of Peginterferon Alfa-2a.

Until now, NADFC of the Republic of Indonesia, as the National Center of Pharmacovigilance, has not received the case-report related to the risk of facial palsy on the use of Peginterferon Alfa-2a. NADFC conveys this information to healthcare professionals to raise awareness and as a consideration in prescribing medicinal products containing Peginterferon Alfa-2a.

NADFC as the National Center of Pharmacovigilance calls for healthcare professionals to submit a report when encountering any adverse event or adverse drug reaction (AE/ADR) using MESO Yellow Form or report online to NADFC through the sub-site http://e-meso.pom.go.id. The AE/ADR report data is needed to safeguard the safety of marketed products in Indonesia, therefore NADFC can do the evaluation, and safety information on drugs can be provided to patients based on population data in Indonesia.

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