BADAN POM

BADAN PENGAWAS OBAT DAN MAKANAN

Jl. Percetakan Negara No. 23 Jakarta Pusat 10560 Indonesia
Telp. (021) 4244691, 4209221, 4263333, 4244755, 4241781, 4244819; Fax : (021) 4245523
Email : infopom@indo.net.id; Website : www.pom.go.id

INFORMATION FOR HEALTHCARE PROFESSIONAL

Beta Interferon: Thrombotic Microangiopathy (TMA) dan Nephrotic Syndrom Risks

Interferon belongs to the endogenic glycoprotein group that acts as immunomodulation agent, anti-virus and anti-proliferative. Beta interferon is indicated for multiple sclerosis recurrence.

In Indonesia, the product is approved to circulate under the trademarks Betaferon (Beta Interferon 1-b has been in circulation since 2007) and Rebif (Beta Interferon 1-a has been in circulation since 2009). Thrombotic microangiopathy (TMA) has been included in the product information and approved in Indonesia.

The NADFC has not received any adverse drug reaction reports involving the use of beta interferon yet. Out of 672 reports in the WHO Global ICSR database regarding this drugs are 4 cases about TMA and 8 cases about nephrotic syndrome - all are related to the use of beta interferon.

On October 14, 2014 Medicines and Healthcare Products Regulatory Agency (MHRA) published Drug Safety Update on beta interferon as a result of a review on TMA and nephrotic syndrome cases report involving the use of beta interferon in Europe. MHRA recommended that healthcare professionals pay attention to early signs/symptoms of thrombotic microangiopathy (TMA) and nephrotic syndrome:

- Thrombotic Microangiopathy
  - Take cautions when signs and symptoms of thrombotic microangiopathy appear. The clinical descriptions of thrombotic microangiopathy include thrombocytopenia, hypertension, fever, central nervous systems symptoms like felling confused and paresis, and kidney function impairment.
  - If clinical signs of thrombotic microangiopathy is observed, run tests to check blood platelet count, lactate dehydrogenase serum count, and kidney functions. Also run a blood smear test for red blood fragment.
  - If diagnosed with thrombotic microangiopathy, provide immediate treatment (consider performing blood plasma exchange procedure) and immediately discontinue the use of beta interferon.

- *Nephrotic Syndrome*
  - Periodically monitor kidney functions.
  - Take cautions for early signs and symptoms of nephrotic syndromes like edema, proteinuria, and kidney function impairment, especially in patients with high risk of kidney disorder.
  - If nephrotic syndrome occurs, handle immediately and consider discontinuing the use of beta interferon.

Thrombotic Microangiopathy (TMA) and nephrotic syndrome can occur within weeks to years after beta interferon treatment is given.

Health Canada has reviewed the drug safety data in Canada and from one of the producers of products containing beta interferon. Based on the evidence, Health Canada decided that there have been TMA risk potentials in the use of beta interferon. Therefore, Health Canada has demanded that beta interferon manufacturers revise the product information by inserting TMA risks for products circulating in Canada. TMA and nephrotic syndrome risks have been inserted in product information in Canada.

The Indonesian NADFC conveys this information to improve the healthcare professionals awereness and to become guidance in prescribing products containing beta interferon and to advise health professionals to monitor early signs/symptoms of TMA and nephrotic syndrome. Healthcare professionals are advised to report adverse drug reaction to the Indonesian NADFC by using the yellow form or by making online reports to the *e-meso* sub-site (http://e-meso.pom.go.id). The data from the adverse drug reaction reports is needed to ensure the safety of products marketed in Indonesia, can be evaluated and drug safety profile based on the Indonesia population can be obtained.

The NADFC will continuously monitor drug safety to provide an optimum protection to the public health, and to ensure product safety for drugs marketed in Indonesia.