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INFORMATION FOR HEALTHCARE PROFESSIONAL

The Risks of Fanconi Syndrome and Zoledronic Acid

On December 30, 2015, Singapore Health Sciences Authority (HSA) published safety information on possible Fanconi syndrome risks associated with zoledronic acid. The safety information was allegedly due to a report of a local Fanconi syndrome on the use of zoledronic acid received by HSA-Singapore. Patients experienced imbalances of several electrolytes including hypocalcaemia, hyposphosphatemia, hypokalemia and low uric acid levels after 10 days of receiving a single dose of intravenous infusion Zoledronic acid 4 mg for secondary bone metastases with prostate cancer. At the time this case was reported in Singapore, the patients still have not recovered and still need oral replacement therapy. Several cases of Fanconi syndrome induced by zoledronic acid have also been published in the literature, reported that fanconi syndrome in patients improved after zoledronic acid was discontinued.

Fanconi syndrome is a renal proximal tubules disorder that causes kidneys to lose glucose, protein, bicarbonate, calcium, uric acid, amino acids and other organic compounds. Clinical symptoms of Fanconi syndrome includes amino aciduria, organic aciduria, low molecular weight proteinuria, hypophosphatemia, normoglycemic glycosuria, metabolic acidosis, hyperuricemia, hypokalemia, and polyuria. In some patients, they only show some of these symptoms. In relation to this safety information, health professionals are recommended to be aware of the clinical symptoms of Fanconi syndrome and to monitor renal function strictly in patients prescribed with zoledronic acid in order to avoid potential drug nephrotoxicity.

Until now, Indonesian NADFC has not received reports on adverse drug reaction related to the use of zoledronic acid yet. The approved zoledronic acid product information in Indonesia has included the risk of renal function impairment in the "warning & precautions" and "adverse drug reaction" sections but has not specified the risk of Fanconi syndrome.

To improve caution, NADFC conveys this information to health professionals. Health professionals are requested to pay attention to the recommendation and report drug side effects to NADFC using the MESO yellow form or by online via e-meso subsite (http://e-meso.pom.go.id).