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

Risk of Respiratory Depression on the Use of Drug Containing Tramadol in Children

An article entitled "A case of respiratory depression in a child with ultra-rapid CYP2D6 metabolism after tramadol" posted in Pediatric Journal on February 2, 2015 has reported that a serious respiratory depression was experienced by a 5-year old child with genotype of ultra-rapid metabolizers CYP2D6 and obstructive sleep apnoea syndrome after having tramadol as a painkiller following the tonsillectomy procedure.

Tramadol is an opioid analgesic indicated to ease an acute chronic pain and also pain after surgery. Inside the body, tramadol is changed CYP2D6 enzyme into an active opioid called O-desmethyltramadol. A phenomenon called Enzyme Polymorphism of CYP2D6 produces poor, intermediate and extensive or ultra-rapid of CYP2D6 metabolizers. Ultra-rapid CYP2D6 metabolizer can increase O-desmethyltramadol concentration to trigger adverse drug reactions that can be life threathening, such as a severe respiratory depression.

Related to safety issue mentioned above, On September 21, 2015 US-FDA released a Drug Safety Communication concerning difficult breathing risk resulted from the use of tramadol as a pain killer for children under 17 years old. FDA does not agree to the use of tramadol for children. Nevertheless, data shows that this drug is "off labeling used" for children. Currently, FDA is evaluating all available information and will provide the final summary and recommendation to public when the evaluation process has finished.

On November 2015, Health Canada released recent safety information related to an international case report that was a respiratory depression on children with Ultra-rapid CYP2D6 metabolism following the use of tramadol. In Canada, tramadol is not recommended to be used for patient under 18 years old. Health Canada, is now evaluating all safety information, and will report the final summary and follow-up steps taken when the evaluation has completed.

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A respiratory depression can also occur when tramadol is used more than the recommended dosage, and when it is used together with other drugs functioning to depress central nervous system (anti-depressants). When respiratory depression caused by the excessive dosage, it can be neutralized by using Naloxone.

Until now, NADFC-RI, Center of Pharmacovigilance, has not received reports on cases respiratory depression or breathing difficulty on tramadol use. NADFC disclose this information to healthcare professionals to raise their awareness and to consider when prescribing the drug.

NADFC, National Center of Pharmacovigilance urges that healthcare professionals make reports on adverse drug reaction using Yellow Form or make an online report at http://e-meso.pom.go.id. With enough data, the safety of marketed products in Indonesia can be evaluated and patients can be informed about safety profile of the drug based on population data in Indonesia.

NADFC will continuously monitor the safety of drugs in order to provide optimum protection for the public health, and to ensure the safety of drugs marketed and distributed in Indonesia.