DRUG ALERT

Naropin: Safety and efficacy not established in children under 1 year of age

The National Adverse Event Monitoring Centre (NADEMC) of the Medicines Control Council wishes to draw the attention of health practitioners to the fact that Naropin (ropivacaine) is not approved for use in children under 1 year of age, as safety and efficacy in this population have not been established.

For paediatric use ropivacaine is approved for acute pain management using caudal epidural or peripheral nerve block in the pre- and postoperative setting.[1] Safety and efficacy have not been established in children under the age of 1 year. The package insert gives no dose for children under 1 year of age.

The NADEMC has a total of 21 adverse reaction reports with 47 adverse reaction terms in its database where ropivacaine is indicated as the medicine suspected to have caused the event. Three of these reports followed the use of ropivacaine in infants less than 1 year of age:

- A 2-month-old male infant (2.1 kg) was given a caudal block with ropivacaine, and 13 minutes later developed apnoea, bradycardia and pallor. He responded to treatment with oxygen and atropine. He required no further treatment apart from tactile stimulation and aminophylline. This infant had been born at 28 weeks' gestation and had a history of apnoeic spells.
- A 2-month-old male infant (2.5 kg) experienced apnoea followed by bradycardia and cyanosis 5 minutes after ropivacaine administration for caudal block. He recovered on treatment. The infant had been born prematurely, but had no history of apnoea.
- A 6-month-old infant (7.8 kg), treated with ropivacaine for postoperative analgesia by epidural infusion over 2 days, was noted to be jittery with continuous abnormal movements of the upper limb, which were more pronounced when he was awake. The symptoms slowly resolved after the infusion was stopped. Analysis of blood samples showed ropivacaine levels below those expected to result in systemic toxicity based on findings in adults.

In all three cases the events were assessed as possibly having been causally associated with Naropin because of the temporal relationship to its administration. The role of other causes, including the clinical status of the infants, could not be excluded.

The systemic toxicity of local anaesthetics, including ropivacaine, mainly involves the central nervous system (CNS) and the cardiovascular system. Excitation of the CNS may be manifested by restlessness, excitement, nervousness, paraesthesiae, dizziness, tinnitus, blurred vision, nausea and vomiting, muscle twitching and tremors, and convulsions. Excitation may be transient and followed by depression with drowsiness, respiratory failure and coma. Cardiovascular system effects of local anaesthetics include myocardial depression and peripheral vasodilatation resulting in hypotension and bradycardia, arrhythmias and cardiac arrest.

Health care professionals are requested to report any suspected reactions associated with the use of Naropin or any other medicines to the National Adverse Drug Event Monitoring Centre at (021) 447-1618, fax (021) 448-6181.

National Adverse Drug Event Monitoring Centre
Medicines Control Council

1. Sweetman C, Blake PS, eds. *Martindale: The Complete Drug Reference*. 33rd ed. London: Pharmaceutical Press, 2002.