

ANOTHER SUCCESS FOR THE GOODMAN PEDIATRIC FORMULATIONS CENTRE OF THE CHU STE-JUSTINE: TWO FORMULATIONS OF LEVETIRACETAM ARE NOW AVAILABLE IN CANADA AND INDICATED FOR USE IN CHILDREN

Access to the oral and intravenous (IV) formulations were made possible by the efforts of the team at the Goodman Pediatric Formulations Centre of the CHU Sainte-Justine (GPFC), and is another important step towards greater access to child-friendly medicines in Canada.

Levetiracetam, one of the most commonly used anti-epileptic agents for children, is now available in Canada as 100mg/mL oral solution, just a few months after the launch of the 100mg/mL solution for injection. Both formulations are [approved for use in children](#) as young as 1 month of age, who have epilepsy.

Even if levetiracetam has been available as tablets since 2003, it was not indicated for use in children until the end of 2019, despite the fact that it had been approved for pediatric use in the US and Europe, as an oral solution for more than 17 years, and as an injectable for more than 13 years. In Canada, during that period, IV levetiracetam could only be accessed on a patient by patient basis through Health Canada's Special Access Program, and the oral solution was only available through pharmacy compounding.

The GPFC had identified levetiracetam as a priority and worked with a pharmaceutical company to facilitate regulatory approval of child-friendly formulations for this much needed medicine in epilepsy.

“When we discuss the mandate of the GPFC, levetiracetam was commonly identified as one of the most requested medications by pediatricians and pharmacists,” said Dr. Catherine Litalien, Medical and Scientific Director and a Co-Founder of the GPFC. “Given that there has been a need for levetiracetam over the last decade, the pediatric community is thrilled that an oral liquid and an IV formulation are now available for our Canadian children,” Dr. Litalien added.

Canada is lagging behind but with these successes it can begin to catch up to other G7 countries

At this time, Health Canada does not require, nor provide incentives, for pharmaceutical companies to market pediatric formulations in Canada, even if they are commonly prescribed and/or are marketed elsewhere.

“The three formulations recently made available to Canadian children, oral and IV solutions of levetiracetam and [previously announced oral solution of amlodipine](#), are important breakthroughs for the thousands of children, their families and health care providers who will benefit from having access to formulations adapted for kids. Continuing to work with industry to facilitate the commercialization of these pediatric-friendly medicines is critical, as inherent market forces often do not make the marketing of these medications in Canada viable.” said Andrea Gilpin, General Manager of the GPFC.

Children are not small adults, they need tailored medicine

"Levetiracetam, for injection, has significantly improved the ability to properly manage decompensation of epilepsy in pediatric patients and to adequately treat these children, when an oral route of



administration is inappropriate. This therapeutic option has been available for many years in other countries, and was long overdue for our Canadian patients. I would like to acknowledge the contribution of the GPFC in this matter,” added Dr. Philippe Major, Pediatric Neurologist from the Sainte-Justine University Hospital Centre.

“It’s important for clinicians to have greater access to paediatric formulations of newer anti-seizure medications for Canadian children. Thank you to the GPFC for undertaking this critical work,” noted Dr. Steven Miller, Head of the Division of Neurology, The Hospital for Sick Children (SickKids).

Source:

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