



FIRST CHILD-FRIENDLY FORMULATION OF AMLODIPINE IS NOW AVAILABLE FOR CANADIAN CHILDREN

This breakthrough was made possible by the efforts of the team at the Goodman Pediatric Formulations Centre of the CHU Sainte-Justine (GPFC), and is a first step towards greater access to child-friendly medicines in Canada.

The GPFC is proud to announce to its partners and network that one of the medications identified on its priority list is now accessible to pediatric patients.

Amlodipine, one of the most used antihypertensive agents in pediatrics is now available for the thousands of children who require this medication each year. Even if it has been available for adults since 1993 as a tablet, amlodipine was never adapted for pediatric use despite its prescription rates for kids. Currently, 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 GPFC, identified amlodipine as a priority, and worked with a pharmaceutical company to facilitate regulatory approval of a child-friendly formulation.

“The fact that amlodipine was first approved in 1993 in Canada as a tablet for use in adults, and as a pediatric formulation since 2015 in the United Kingdom, illustrates how Canada lags behind in providing access to child-friendly formulations,” said Dr. Catherine Litalien, Executive Director and a Co-Founder of the GPFC. “The GPFC is thrilled that an oral liquid formulation of amlodipine is now available in Canada, given that it is commonly used in pediatrics,” Dr. Litalien added.

All other G7 countries perform better than Canada in that area

There are no pediatric-specific guidelines, incentives or fee structures, which exist today to encourage the marketing of pediatric formulations in Canada. In this regard, Canada ranks last among G7 countries.

“This is an important milestone for the thousands of children, their families and health care providers who will benefit from having access to a safe oral liquid formulation. We have identified 56 medications that need to be adapted for Canadian children. Access to such formulations is of national importance and it can be resolved through Federal regulatory changes.” said Andrea Gilpin, General Manager of the GPFC.

Children are not small adults, they need tailored medicine

“Having safe and effective pediatric formulations adapted to the needs of Canadian children is critical to the delivery of high quality of care, and represents a priority for our members and



the families they serve” stated Ms. Emily Gruenwoltd, President & CEO at Children’s Healthcare Canada/Executive Director of the Pediatric Chairs of Canada. “The availability of amlodipine announced today, attests to the national leadership and significant strides that the GPFC has made, in partnership with the children’s healthcare community, in advocating for change to increase access to pediatric formulations in Canada,” Ms. Gruenwoltd concluded.

"Having liquid amlodipine available for Canada's children is an excellent step forward and a tribute to the hard work of the people at the GPFC in collaboration with Health Canada to bring child-friendly medications available in other countries to Canada. It is hoped that this is the first step of many in enhancing optimal drug therapy for Canada's children," stated Dr. Michael Rieder, CIHR-GSK Chair in Paediatric Clinical Pharmacology, Western University.

"The development of a child-friendly Amlodipine formulation is a significant advancement in the pediatric health care community’s longstanding mission to ensure children have evidence-based prescription rates. Through the hard work of the GPFC, clinicians and family doctors across Canada can now safely prescribe this treatment , which to date has not been available to children. This is a significant step forward in improving pediatric therapy and the overall health of children in Canada. MICYRN and KidsCan Trials are extremely supportive of the GPFC’s mandate, and look forward to continue collaborating where needed in this important endeavor. Thank you to the GPFC for their incredible leadership," stated Dr. Thierry Lacaze, Scientific Director, MICYRN Network Lead, KidsCan Trials.

Source:

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