

Health Canada approves DUPIXENT® (dupilumab injection) as the first biologic for the treatment of moderate-to-severe atopic dermatitis in children aged 6 to 11 years

- DUPIXENT® is the only biologic medicine approved to treat atopic dermatitis for this patient population.
- Fifth indication for DUPIXENT® in Canada following approvals for moderate-to-severe atopic dermatitis in adults and adolescents, severe chronic rhinosinusitis with nasal polyposis, and severe asthma in adults and adolescents.
- For those living with atopic dermatitis, itch has the highest impact on a patient's quality of life.¹
- Results from a survey conducted among Canadian children with atopic dermatitis found that 70 per cent experienced loss of sleep and 30 per cent experienced anxiety due to their condition.²

MISSISSAUGA, ON, Feb. 23, 2021 /CNW/ - Sanofi Canada announced today that Health Canada has approved DUPIXENT® (dupilumab injection) for the treatment of moderate-to-severe atopic dermatitis (AD) in children aged six to 11 years whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.³

"As the first biologic treatment for atopic dermatitis approved for this age group, DUPIXENT® is a promising new option for treating children living with this chronic disease," says Dr. Melinda Gooderham, Dermatologist and Medical Director at the SKiN Centre for Dermatology.

"Because it targets type 2 inflammation, the underlying cause of the disease, it may help young patients gain more control over their symptoms during childhood, a pivotal time in their development."



DUPIXENT® is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) proteins and is not an immunosuppressant. Data from DUPIXENT® clinical trials have shown that IL-4 and IL-13 are key drivers of the type 2 inflammation that plays a major role in AD, asthma, and severe chronic rhinosinusitis with nasal polyposis (CRSwNP).⁴

AD, the most common form of eczema, is an inflammatory disease classified by dry, itchy skin. In its moderate-to-severe form, it is characterized by rashes that can cover much of the body, and can include intense, persistent itching, skin lesions and skin dryness, cracking, redness or darkness, crusting and oozing.⁵ Inadequately controlled AD can have a physical, emotional and psychosocial impact, causing sleep disturbance, symptoms of anxiety and depression, and feelings of isolation.⁶

For children living with AD, studies showed that the impact extends beyond its physical symptoms. A survey conducted by the Eczema Society of Canada among Canadian children from infancy up to the age of 18 (and their caregivers) living with AD found that 70 per cent experienced loss of sleep due to their condition, 20 per cent missed school days and 30 per cent experienced anxiety.⁷ These factors can have a negative psychological impact on children, particularly in regard to their concentration and performance at school along with their willingness to socialize.⁸

"Atopic dermatitis is a chronic disease that has an indelible impact on all patients, both physically and psychologically, and can be devastating to children during a vulnerable time in their life," says Marissa Poole, Country Lead, Sanofi Canada and General Manager, Sanofi Genzyme Canada. "With this new indication, DUPIXENT® now has the potential to help the many Canadians who experience this disease including children, adolescents and adults."

About DUPIXENT®

Since its initial approval in 2017, DUPIXENT® remains the only biologic medicine approved by Health Canada for the treatment of patients six years and older with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.⁹ DUPIXENT® is also approved in Canada for the treatment of adult patients with severe CRSwNP and for the treatment of severe asthma in patients 12 years and older.¹⁰

DUPIXENT® is jointly developed by Sanofi and Regeneron under a global collaboration agreement.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi entities in Canada employ approximately 2,000 people. In 2018, we invested more than \$127 million in R&D in Canada, creating jobs, business and opportunity throughout the country.

Follow us on Twitter [@SanofiCanada](#) and on [YouTube](#).

Sanofi, Empowering Life

References

¹ Ben-Gashir MA, Seed PT, Hay RJ. Quality of life and disease severity are correlated in children with AD. *Br J Dermatol*. 2004;150(2):284-90. Available from <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2133.2004.05776.x?sid=nlm%3Apubmed>. Accessed February 19, 2021.

² Eczema Society of Canada. Atopic Dermatitis Quality of Life Report. Available from https://eczemahelp.ca/wp-content/uploads/2019/02/ESC_Quality-of-Life-Report_Nov-2017-1.pdf. Accessed February 19, 2021.

³ DUPIXENT[®] Canada Product Monograph. February 22, 2021.

⁴ DUPIXENT[®] Canada Product Monograph. February 22, 2021.

⁵ Mount Sinai. Patient Care Atopic Dermatitis. Available from <http://www.mountsinai.org/patient-care/health-library/diseases-and-conditions/atopic-dermatitis#risk>. Accessed February 19, 2021.

⁶ Eczema Society of Canada. Atopic Dermatitis Quality of Life Report. Available from https://eczemahelp.ca/wp-content/uploads/2019/02/ESC_Quality-of-Life-Report_Nov-2017-1.pdf. Accessed February 19, 2021.

⁷ Eczema Society of Canada. Atopic Dermatitis Quality of Life Report. Available from https://eczemahelp.ca/wp-content/uploads/2019/02/ESC_Quality-of-Life-Report_Nov-2017-1.pdf. Accessed February 19, 2021.

⁸ Sick Kids. Eczema: School and activities. Available from <https://www.aboutkidshealth.ca/Article?contentid=1113&language=English>. Accessed February 19, 2021.

⁹ DUPIXENT[®] Canada Product Monograph. February 22, 2021.

¹⁰ DUPIXENT[®] Canada Product Monograph. February 22, 2021.

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