

Health Canada approves Lovenox® for the prevention of blood clot formation in the extra-corporeal circulation during hemodialysis in patients with end stage kidney disease (ESKD)

Studies show that Lovenox® (enoxaparin sodium) is an alternative to conventional heparin in preventing clotting during hemodialysis

Laval, Quebec - September 25, 2018 – Sanofi Canada announced today Health Canada’s approval of a new indication for Lovenox® (enoxaparin sodium) for the prevention of thrombus formation in the extra-corporeal circulation during hemodialysis in patients with end stage kidney disease (ESKD). This latest approval was based on a submission relying on third-party data demonstrating comparative safety and efficacy of Lovenox® with unfractionated heparin (UFH) in ESKD patients undergoing dialysis.

“Patients with end-stage kidney disease undergoing hemodialysis require optimal care including proper hemodialysis technique and an effective anticoagulant to prevent thrombosis in the blood circuit,” says Dr. Susan Kahn, Clinical Epidemiologist and Internist at Jewish General Hospital in Montreal, Co-Director of the CanVECTOR Network and Founder and Director of the Centre of Excellence in Thrombosis and Anticoagulation Care (CETAC). “With 25 years of experience with Lovenox® in the treatment and prevention of venous thromboembolism in patients, this new indication is a welcome addition to the current treatment landscape.”

End stage kidney disease is a condition in which the kidneys are permanently impaired and can no longer function normally to maintain life.[\[i\]](#) One in 10 Canadians has kidney disease, and millions more are at risk.[\[ii\]](#) The number of Canadians living with ESKD has grown 36% since 2007 with 47% of new patients under the age of 65.[\[iii\]](#)

“Anticoagulation is an important component of the dialysis procedure,” says Dr. Gordon Wong, Nephrologist, Trillium Health Partners, Mississauga. “The addition of Lovenox® to current therapeutic options will help simplify and allow for more precision anticoagulation strategies to optimize the care of patients with end stage renal disease.”

Lovenox® was initially approved for hemodialysis in 1987 in France. It is approved for hemodialysis in 117 countries including France, Germany, Australia, Spain, Israel, Ireland, UK and now Canada.

“This approval represents Sanofi Canada’s long-time commitment to thrombosis care,” says Dr. Sophia Kajla, Sanofi Canada Head of Medical Affairs for General and Established Medicines. “With incident rates of ESKD increasing over time, the need for optimal dialysis and patient care is crucial. As a world leader in thrombosis treatment and prevention, we are proud to put patients first, to ensure they receive the proper treatment at the right time for the right condition.”

About End Stage Kidney Disease (ESKD) in Canada

End stage kidney disease is a condition in which the kidneys are permanently impaired and can no longer function normally to maintain life[\[iv\]](#). In 2014, kidney disease was the 11th leading cause of death in Canada.[\[v\]](#) One in 10 Canadians has kidney disease, and millions more are at risk. The principal cause of end-stage chronic kidney disease is diabetes[\[vi\]](#). In 2014, there were 35 281 Canadians (excluding Quebec) living with end-stage kidney disease (ESKD), 58.6% (20 690) of whom were receiving some form of dialysis.[\[vii\]](#) Patients on dialysis require a significant amount of health care resources. The total annual cost to care for a patient on dialysis ranges from \$56,000 to \$107,000 per year, depending on the type of dialysis treatment.[\[viii\]](#)

About Lovenox®

Lovenox® (enoxaparin sodium) is a unique chemical entity in a class of antithrombotic agents known as low-molecular-weight heparins (LMWH). The number one selling low-molecular-weight heparin in the world, Lovenox® is obtained by alkaline degradation of heparin benzyl ester and is about one-third the molecular size of unfractionated heparin (UFH). It is used to inhibit clot formation in venous or arterial vessels to avoid potential acute or chronic complications of venous or arterial thrombosis such as pulmonary embolism, myocardial infarction or death of cardiovascular origin. This has been demonstrated by more than 25 years of use in the treatment of 130 million patients in 96 countries.

About Sanofi - www.sanofi.ca

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 1,900 people. In 2017 we invested over \$123 million in R&D in Canada, creating jobs, business and opportunity throughout the country.


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[i] (<https://www.cihi.ca/en/incident-end-stage-kidney-disease-patients-corr-data>)

[ii] The Kidney Foundation of Canada. <https://www.kidney.ca/file/Facing-the-Facts-2018-CKD-infographic.pdf>

[iii] The Kidney Foundation of Canada. <https://www.kidney.ca/file/Facing-the-Facts-2018-CKD-infographic.pdf>

[iv] (<https://www.cihi.ca/en/incident-end-stage-kidney-disease-patients-corr-data>).

[v] Statistics Canada, Deaths and cause of deaths , 2014 <https://www150.statcan.gc.ca/n1/en/daily-quotidien/171116/dq171116c-eng.pdf?st=GBqe3-8w>

[vi] The Kidney Foundation of Canada. <https://www.kidney.ca/file/Facing-the-Facts-2018-CKD-infographic.pdf>

[vii] [https://secure.cihi.ca/free_products/2016_CORR_Snapshot_EN\(web\).pdf](https://secure.cihi.ca/free_products/2016_CORR_Snapshot_EN(web).pdf)

[viii] The Kidney Foundation of Canada. <https://www.kidney.ca/file/Facing-the-Facts-2018-CKD-infographic.pdf>. Accessed August 2018.
