NEW indication for Ozempic®: MACE risk reduction

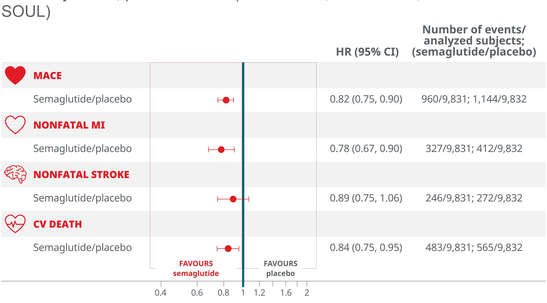
Ozempic® (semaglutide injection) is indicated as an adjunct to diet, exercise, and standard of care to reduce the risk of **major adverse cardiovascular events** (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with **type 2 diabetes** and **established cardiovascular disease and/or chronic kidney disease**.[1]

CV outcomes: MACE and its components (nonfatal MI, nonfatal stroke, CV death)

Results for the composite endpoint of MACE and its components were derived from a pooled analysis of four studies: SUSTAIN 6 and FLOW (with Ozempic® subcutaneous injection), and PIONEER 6 and SOUL (with oral semaglutide).* Each individual trial was supportive of a risk reduction in MACE, although there were some inconsistencies across trials with respect to results for each MACE component due to limited number of events for individual components in each study).[1]

Time from randomization to first EAC-confirmed MACE and components

Full analysis set, pooled studies (PIONEER 6, SUSTAIN 6, FLOW and SOUL)



Adapted from the Product Monograph.

Data from the in-trial period. The time-to-event endpoint was analyzed using a Cox regression proportional hazards model with treatment as a fixed factor. The model was stratified by study.
CI, confidence interval; CV, cardiovascular; EAC, event adjudication committee; HR, hazard ratio; MACE, major cardiovascular event; MI, myocardial infarction.

MACE:
With semaglutide SC injection or oral
18% reduced risk of MACE shown vs. placebo
HR 0.82 (95% CI 0.75, 0.90)

Nonfatal stroke component was not statistically significant.

Semaglutide shows a positive risk-benefit profile for the reduction of risk of MACE in T2D patients with CVD and/or CKD

Based on cumulative data from >9,800 semaglutide treated patients in the four outcome trials, as well as supportive data from semaglutide studies for other indications (e.g., SC semaglutide for weight management).

Want to learn more about the MACE pooled analysis?

See Product Monograph **Visit ozempic.ca†**

Ozempic® is indicated for the once-weekly treatment of adult patients with type 2 diabetes mellitus to improve glycemic control in combination with metformin, when diet and exercise plus maximal tolerated dose of metformin do not achieve adequate glycemic control.[1]

Ozempic® is indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, and cardiovascular death in adults with type 2 diabetes and chronic kidney disease.[1]

Not a substitute for insulin. Not for use in type 1 diabetes or for the treatment of diabetic ketoacidosis. Ozempic® is not indicated for use in pediatric patients.

Contraindications:
- Personal or family history of medullary thyroid carcinoma (MTC), or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- Hypersensitivity to Ozempic® or to any of the product components
- Pregnancy or breastfeeding

Most serious warnings and precautions:
Risk of thyroid C-cell tumours: In both genders of rats and mice, semaglutide caused treatment-dependent thyroid C-cell tumours. Patients should be counselled regarding the risk and symptoms of thyroid tumours.

Other relevant warnings and precautions:
- Should not be administered intramuscularly
- CV effects: Increased heart rate; PR interval prolongation; no therapeutic experience in patients with congestive heart failure NYHA Class IV
- Use in patients with a history of severe gastroparesis; more serious/severe GI adverse events may be experienced, use with caution
- Hypoglycemia with concomitant use of insulin secretagogues or insulin
- Use with other incretin drugs
- Hepatic insufficiency
- Pancreatitis
- Hypersensitivity
- Diabetic retinopathy: In patients with history of disease, monitor for progression
- Aspiration in association with general anaesthesia or sedation
- Renal impairment: Severe GI adverse reactions warrant monitoring of renal function; use in end-stage disease
- Driving and operating machinery
- Dizziness (initial dose escalation)
- GLP-1 RA class potential for severe GI disease (ileus)
- Acute events of gall bladder disease

For more information:
Consult the Ozempic® Product Monograph at OzempicPM-E.ca for more information relating to adverse reactions, drug interactions, and dosing information, which have not been discussed in this piece.

The Product Monograph is also available by calling us at 1-800-465-4334.

CI, confidence interval; CKD, chronic kidney disease; CV, cardiovascular; eGFR, estimated glomerular filtration rate; GLP-1 RA, glucagon-like peptide-1 receptor agonist; MACE, major adverse cardiovascular event; MI, myocardial infarction; T2D, type 2 diabetes; uACR; urine albumin-creatinine ratio.

* **SUSTAIN 6 CV safety outcomes trial:** 104-week, randomized, double-blind, placebo-controlled, parallel-group trial in 3,297 patients with T2D and high CV risk receiving Ozempic® 0.5 mg, Ozempic® 1 mg or placebo (n=1,649) + standard of care. Primary objective: to confirm that treatment with semaglutide does not result in any unacceptable increase in cardiovascular risk as compared to placebo in adults with type 2 diabetes.[1]
FLOW kidney outcomes trial: Multinational, randomized, placebo-controlled, double-blind, parallel-group, event-driven trial to determine the effect of Ozempic® vs. placebo in 3,533 adults with T2D and CKD (eGFR 25-75 mL/min/1.73 m^2, uACR >100 mg/g and <5,000 mg/g) receiving Ozempic® 1 mg or placebo. 40.9-month median follow-up. Primary objective: to demonstrate that Ozempic® delays the progression of renal impairment and lowers the risk of renal and CV mortality vs. placebo + standard of care, in adults with T2D and CKD.[1]
PIONEER 6 CV safety outcomes trial: Multinational, placebo-controlled, double-blind trial in 3,183 patients with T2D and CVD receiving oral semaglutide 14 mg once daily or placebo + standard of care. Primary endpoint: time to first occurrence of a three-part MACE composite outcome, which included CV death, nonfatal MI and nonfatal stroke.[1]
SOUL CV outcomes trial: Randomized, double-blind, parallel-group, placebo-controlled trial in 9,650 patients with T2D and established CVD and/or CKD) receiving oral semaglutide 14 mg once daily or placebo + standard of care. Primary endpoint: MACE; time to first occurrence of a three-component composite outcome, which included CV death, nonfatal MI and nonfatal stroke.[1]
† Ozempic.ca is open to the general public.

Reference: 1. Ozempic® (semaglutide injection) Product Monograph. Novo Nordisk Canada Inc., February 25, 2026.

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www.novonordisk.ca

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