Rx

ADVERTISEMENT

QUESTIONS·ANSWERS

ABOUT Pr OZEMPIC® semaglutide injection

When metformin alone is no longer enough, think Ozempic®

What is Ozempic®?

Ozempic® (semaglutide injection) is a once-weekly medication that may help improve blood sugar in adults with Type 2 diabetes.[1]

Indication

Ozempic® is indicated for the once-weekly treatment of adult patients with type 2 diabetes mellitus (T2DM) 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]

How is Ozempic® supplied?

Ozempic® is supplied in pre-filled FlexTouch® pens. NovoFine® Plus needles are included in every carton.

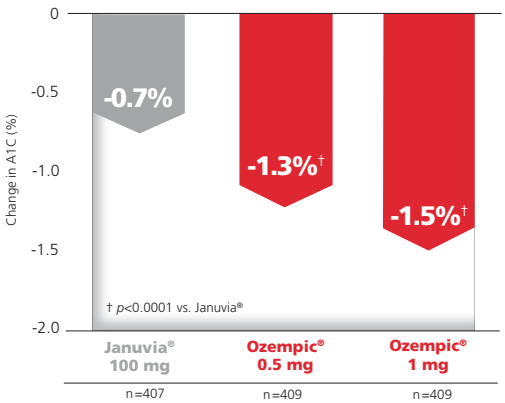
Dosage form	Volume per pen	Intended use	Per carton
0.25 mg or 0.5 mg	1.5 mL	Dose escalation and maintenance treatment at the 0.5 mg dose	1 pen + 6 NovoFine®Plus needles
1 mg	3 mL	Maintenance treatment at the 1 mg dose only	1 pen + 4 NovoFine® Plus needles

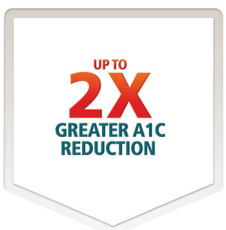
What was the efficacy of Ozempic® in clinical trials?

DEMONSTRATED A1C REDUCTION

At week 56, both as add-on to metformin and/or TZD, **Ozempic® demonstrated statistically significantly greater A1C reduction vs. Januvia®.**[1‡]

Mean change from baseline in A1C at week 56





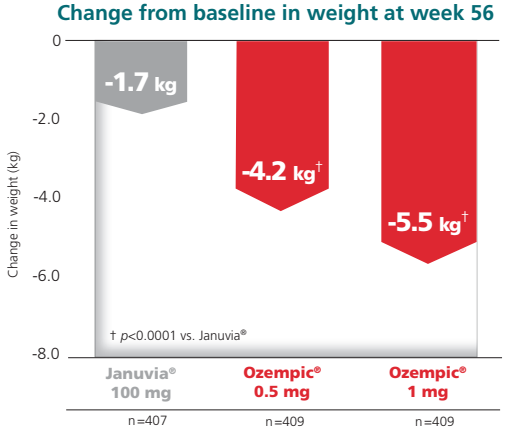
SHOWN WITH OZEMPIC® V.S JANUVIA®
(Both as add ons to metformin and or TZD)

Adapted from Product Monograph and Ahrén *et al.*
Mean baseline A1C = 8.1%; baseline A1C (%) Ozempic® 0.5 mg = 8.0; Ozempic® 1 mg = 8.0; Januvia® 100 mg = 8.2.
TZD = thiazolidinedione.

DEMONSTRATED WEIGHT REDUCTION

At week 56, both as add-on to metformin and/or TZD (2° endpoint), **Ozempic® demonstrated statistically significant weight reduction vs. Januvia®.**[1‡]

Change from baseline in weight at week 56



WITH OZEMPIC® V.S JANUVIA®
(Both as add ons to metformin and or TZD; 2nd endpoint)

Adapted from Product Monograph and Ahrén *et al.*
Mean baseline weight: 89.5 kg; TZD= thiazolidinedione.

Ozempic® is not indicated for weight reduction.

‡ A 56-week, randomized, double-blind, double-dummy, active-controlled, parallel-group, multicentre trial to compare the efficacy and safety of Ozempic® vs. Januvia®. A total of 1,231 patients with T2DM inadequately controlled on metformin and/or thiazolidinediones were randomized to receive once-weekly Ozempic® 0.5 mg (n=409), once-weekly Ozempic® 1 mg (n=409), or once-daily Januvia® 100 mg (n=407). At week 56, the primary endpoint was change in A1C and the secondary endpoint was change in mean body weight at week 30.

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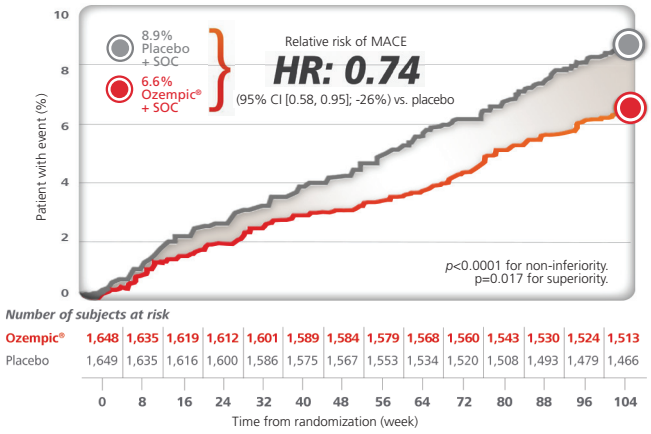
DEMONSTRATED CARDIOVASCULAR OUTCOMES

In addition to standard of care (SOC)[£] in patients with T2DM and at high risk of CV events, **Ozempic® demonstrated a CV outcome (MACE) safety endpoint at 2 years**.[1,2§]

Time to first confirmed major adverse CV event (MACE)



The components of MACE are CV death, non-fatal stroke and non-fatal MI.[1] No increased risk for MACE was observed with Ozempic®.[1] Ozempic® is not indicated to reduce the incidence of CV (MACE) outcomes.

CV=cardiovascular; MACE=major adverse cardiovascular event; HR=hazard ratio; CI=confidence interval; MI=myocardial infarction

What is the dosing and administration for Ozempic®?

Ozempic® provides convenient once-weekly dosing—**any time of the day, with or without meals.**[1]

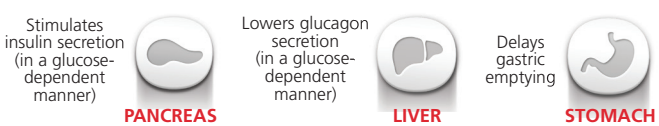
- **Dose escalation:** The starting dose of 0.25 mg is not a therapeutic dose. After 4 weeks, the dose should be increased to 0.5 mg once weekly. If additional glycemic control is needed after 4 weeks, the dose may be increased to 1 mg once weekly to further improve glycemic control (1 mg once weekly is the maximum recommended dose).[1]
- **Dosage adjustment:** No dosage adjustments are required for patients with renal impairment.[1]

See Product Monograph for complete dosing and administration information.

What is the mechanism of action of Ozempic®?[¶]

Ozempic® (semaglutide injection) is a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor. It is a GLP-1 analogue with 94% sequence homology to human GLP-1.[1]

Ozempic®:[1]



GLP-1=glucagon-like peptide-1

What were the most common gastrointestinal (GI) adverse reactions associated with Ozempic®?

The most common GI adverse reactions were nausea (Ozempic® 0.5 mg= 17.0%, Ozempic® 1 mg =19.9%, comparator=6.3%), diarrhea (Ozempic® 0.5 mg=12.2%, Ozempic® 1 mg=13.3%, comparator=5.7%), abdominal pain (Ozempic® 0.5 mg=8.7%, Ozempic® 1 mg=8.1%, comparator= 4.7%), vomiting (Ozempic® 0.5 mg=6.4%, Ozempic® 1 mg=8.4%, comparator=3.3%) and constipation (Ozempic® 0.5 mg=6.9%, Ozempic® 1 mg=6.2%, comparator=2.7%). The majority of the nausea, vomiting and diarrhea events occurred during dose escalation. Investigators graded the severity of gastrointestinal adverse reactions occurring on 0.5 mg and 1 mg of Ozempic® as "mild" in 38.8% and 36.5% of cases, respectively, "moderate" in 9.8% and 12.5% of cases, respectively, or severe in 1.7% and 1.8% of cases, respectively.[1]

Counselling tips to help manage GI side effects:

- ✔ Eat smaller, more frequent meals
- ✔ Eat slowly
- ✔ Drink plenty of water (stay hydrated)
- ✔ Avoid fatty food

See Product Monograph for complete information on adverse events.

Clinical use:
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)
- Pregnancy or breastfeeding

Most serious warnings and precautions:
Risk of thyroid C-cell tumours: In both genders of rats and mice, semaglutide causes 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
- Pancreatitis
- Hypoglycemia with concomitant use of insulin secretagogues or insulin
- Use with other incretin drugs
- Hypersensitivity
- Diabetic retinopathy: in patients with history of disease monitor for progression
- Renal impairment: severe GI adverse reactions warrant monitoring of renal function; use in end-stage disease
- CV effects: increased heart rate; PR interval prolongation
- Hepatic insufficiency

For more information:
Please consult the 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 advertisement. The Product Monograph is also available by calling us at 1-800-465-4334.

£ Standard of care included oral antihyperglycemic treatments, insulin, antihypertensives, diuretics, antithrombotic and lipid-lowering therapies.

§ A 2-year, randomized, double-blind, placebo-controlled, parallel-group trial to evaluate CV and other long-term outcomes of Ozempic®. A total of 3,297 patients with T2DM and high risk of CV events were randomized based on evidence of CV disease, insulin treatment and renal impairment to once-weekly Ozempic® 0.5 mg (n=826), Ozempic® 1 mg (n=822) or placebo (n=1,649) in addition to standard of care treatments, such as oral antihyperglycemic treatments, insulin, antihypertensives, diuretics and lipid-lowering therapies at investigator discretion. The primary endpoint was time from randomization to first occurrence of a major adverse CV event (MACE) defined as CV death, non-fatal myocardial infarction, or non-fatal stroke. Secondary endpoints included first occurrence from baseline to week 104 of the individual components of the composite outcomes and diabetic retinopathy complications; change from baseline to week 104 in body weight and A1C.

¶ Clinical significance has not been established.

References

1. Ozempic® (semaglutide injection) Product Monograph. Novo Nordisk Canada Inc., 2018.
2. Marso SP, *et al.* Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. *N Engl J Med*. 2016;375(19):1834-1844

Pr OZEMPIC® semaglutide injection

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