To Whom It May Concern

13 December 2024

**Novo Nordisk confirms that there is ample availability of Ozempic® 1mg high dose in the market.**

**S4 Ozempic® (1.34mg/ml Semaglutide), 1mg high dose pen.**

**Reg. No.: 53/21.13/0497**

**Therapeutic indication: Ozempic® is indicated:**
a) for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise
• as monotherapy when metformin is considered inappropriate due to intolerance or contraindications.
• as combination therapy with oral anti-diabetic medicines (metformin, thiazoledinediones, sulphonylurea), basal insulin with or without metformin and pre-mix insulin.
b) 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 mellitus and established cardiovascular disease.

Novo Nordisk South Africa does not advocate the use of their products other than as indicated in the locally approved package insert or professional information.

| Nappi Code | Medicine Proprietary Name | Active Ingredients | Strength and Unit | Dosage Form | Pack Size | Quantity | Price Excl VAT | SEP |
|---|---|---|---|---|---|---|---|---|
| 3003249001 | **Ozempic** | Semaglutide | 1.34 mg/ml | PED | 1.5 | 1 | R1,170.69 | R1,346.29 |
| 3003250001 | **Ozempic** | Semaglutide | 1.34 mg/ml | PED | 3 | 1 | R2,341.38 | R2,692.59 |

For additional information or any enquiries, please contact:

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5. Healthcare professionals are urged to report adverse drug reactions (ADRs), or product quality issues to Novo Nordisk (Pty) Ltd via email: za-acandcc@novonordisk.com or call +2783 379 2104. Alternatively, healthcare professionals may complete the ADR reporting by visiting the SAHPRA website and email adr@SAHPRA.org.za
6. Healthcare professionals are advised to refer to the PI/PIL from the SAHPRA repository for the latest approved professional information, which can be found at this link: https://pi-pil-repository.sahpra.org.za

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Yours Sincerely

D Swanepoel

Diabetes BU Head
Donavan Swanepoel

**Ozempic abbreviated PI**
**Scheduling status: S4**
**Name of the medicine: OZEMPIC®**
**Qualitative and quantitative composition**: Semaglutide 1, 34 mg/ml
**Therapeutic indication:** Ozempic® is indicated:
a) for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise
☐ as monotherapy when metformin is considered inappropriate due to intolerance or contraindications.
☐ as combination therapy with oral anti-diabetic medicines (metformin, thiazoledinediones, sulphonylurea), basal insulin with or without metformin and pre-mix insulin.
b) 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 mellitus and established cardiovascular disease.
**Posology and method of administration**: Ozempic® starting dose is 0,25 mg once weekly. After 4 weeks, the dose should be increased to 0,5 mg once weekly. After at least 4 weeks with a dose of 0,5 mg once weekly, the dose can be increased to 1 mg once weekly to further improve glycaemic control. Ozempic® is to be administered once weekly at any time of the day, with or without meals. Ozempic® is to be injected subcutaneously in the abdomen, in the thigh or in the upper arm. The injection site can be changed without dose adjustment. Ozempic® should not be administered intravenously or intramuscularly. The day of weekly administration can be changed if necessary as long as the time between two doses is at least 2 days (>48 hours). When Ozempic® is added to existing sodium-glucose cotransporter 2 (SGLT2) inhibitor therapy, the current dose of SGLT2 inhibitor can be continued unchanged.
**Contraindications**: Hypersensitivity to semaglutide or to any of the excipients, a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2), pregnancy and lactation.
**Special warnings and precautions for use**: Ozempic® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Ozempic® is not a substitute for insulin. Acute pancreatitis has been observed with the use of Ozempic®. Patients should be informed of the characteristic symptoms of acute pancreatitis. If pancreatitis is suspected, Ozempic® should be discontinued; if confirmed, Ozempic® should not be restarted. Patients treated with Ozempic® in combination with a sulfonylurea or insulin may have an increased risk of hypoglycaemia. The risk of hypoglycaemia can be lowered by reducing the dose of sulfonylurea or insulin when initiating treatment with Ozempic®. Risk of Thyroid C-cell Tumours: Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist have been reported in the post marketing period: the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans.
**Interaction with other medicines and other forms of interaction**: *In vitro* studies have shown very low potential for Ozempic® to inhibit or induce CYP enzymes and to inhibit drug transporters. The delay of gastric emptying with Ozempic® may influence the absorption of concomitantly administered oral medicines. The potential effect of Ozempic® on the absorption of co-administered oral medicines was studied in trials at Ozempic® 1 mg steady state exposure.
**Fertility, pregnancy and lactation**: Ozempic® is contraindicated during pregnancy and lactation.
**Undesirable effects**: The most frequently reported adverse reactions with Ozempic® in clinical trials were gastrointestinal disorders, including nausea, diarrhoea and vomiting. Adverse reactions by system organ class and absolute frequencies identified in all phase 3a trials listed here as Very common (≥1/10): Hypoglycaemia when used with insulin or sulfonylurea, nausea, diarrhoea; Common (≥1/100 to <1/10): Hypoglycaemia when used with other OADs, decreased appetite, dizziness, diabetic retinopathy complications, vomiting, abdominal pain, abdominal distension, constipation, dyspepsia, gastritis, gastroesophageal reflux disease, eructation, flatulence, cholelithiasis, fatigue, increased lipase, increased amylase, weight decreased; Uncommon (≥1/1,000 to <1/100): hypersensitivity, dysgeusia, increased heart rate, injection site reactions, hypersensitivity, acute pancreatitis; Rare (≥1/10,000 to <1/1,000): anaphylactic reaction; Frequency unknown: angioedema.
**Overdose:** There is no specific antidote for overdose with Ozempic®. In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A prolonged period of observation and treatment for these symptoms may be necessary, taking into account the long half life of Ozempic® of approximately 1 week.
**Reg. No.**: 53/21.13/0497
For full prescribing information, refer to the Professional Information approved by the Regulatory Authority.