

**Ozempic®  
(semaglutide)  
solution for injection  
1.34 mg/ml**

**Summary of the risk management plan (RMP) for  
Ozempic®**



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# **1 Summary of the risk management plan (RMP) for Ozempic® (semaglutide)**

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them.

The RMP summary of Ozempic® is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the „Arzneimittelinformation / Information sur le médicament“ approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Ozempic® in Switzerland is the „Arzneimittelinformation / Information sur le médicament“ (see [www.swissmedicinfo.ch](http://www.swissmedicinfo.ch)) approved and authorized by Swissmedic.

Novo Nordisk Pharma AG is fully responsible for the accuracy and correctness of the content of the here published summary RMP of Ozempic®.

## **2 Overview of disease epidemiology**

Type 2 diabetes mellitus (T2DM) is a lifelong (chronic) illness where patients have too much sugar in their blood (also called ‘hyperglycaemia’).

T2DM is the most common type of diabetes (9 out of 10 cases). Worldwide, 415 million patients have the illness and the number is rapidly increasing.

T2DM is more common in people over 30 years of age and usually develops slowly. The following can increase the risk:

- Overweight
- Low activity levels
- A high calorie diet
- A family history of the illness.

Consistent high blood sugar damages the blood vessels in different organs and increases the risk of:

- Infections and skin ulcers

- Eye problems or problems with vision
- Nerve and kidney damage
- Cardiovascular diseases and strokes
- Death

Good control of weight, blood sugar, blood pressure, cholesterol levels and a healthy lifestyle is important to limit these medical problems.

### **3 Summary of treatment benefits**

#### **3.1 Current standard of treatment**

Management of T2DM includes changes in lifestyle and taking diabetes medicines (tablets and/or injections). If one type is not enough, a second medicine is added.

At present, there are 2 main types of diabetes medicines that are injected. One is based on a hormone secreted in the pancreas, called insulin. The other is based on a hormone secreted in the gut, called glucagon-like peptide-1 (GLP-1). Ozempic® belongs to the latter group. It helps the body reduce its blood sugar level only when this is too high and can be added in almost any step of the treatment of T2DM, when other antidiabetic medications have failed or the risk of cardiovascular disease is high.

The effects of Ozempic® have been investigated in 8 large studies involving more than 8,000 adults with T2DM. One involved more than 3,000 adults with T2DM who were at an increased risk of cardiovascular diseases.

The results from these studies showed that Ozempic® is effective in lowering the blood sugar and keeping it down for a long time. Additionally, the results of the large study involving adults at an increased risk of cardiovascular diseases showed that Ozempic® is effective in reducing the risk of cardiovascular diseases in adults with T2DM.

### **4 Unknowns relating to treatment benefits**

All relevant patient groups intended to be treated with Ozempic® have been studied.

## 5 Summary of safety concerns

### 5.1 Summary of safety concerns - Important potential risks

Risk	What is known	Preventability
Gallstones (cholelithiasis)	Patients with T2DM have an increased risk of gallstones. Treatment with GLP-1-based medicines, including Ozempic®, increases this risk. Gallstones have been reported in up to 3 in 100 patients taking Ozempic®	The risk can be lowered by eating a healthy diet, exercising regularly and having control over body weight.
Complications to the eye disease commonly seen in patients with diabetes (diabetic retinopathy complications)	Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disease. This is not specific to Ozempic®, but a well-known effect of some types of diabetes treatments like insulin.	Patients with this type of eye disease should have their eyes examined regularly and inform their doctor of any eye problems.

**Abbreviations:** GLP-1 = glucagon-like peptide-1; T2DM = type 2 diabetes mellitus.

### 5.2 Summary of safety concerns – Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
A rare subtype of thyroid cancer which originates from the C-cells in the thyroid (Medullary thyroid cancer [MTC])	When Ozempic® was given to rats and mice for most of their lifetime, more medullary (C-cell) thyroid cancers were seen. The relevance of these findings for humans is considered low. No events of MTC have been reported in patients treated with semaglutide. However, since it is a serious condition, MTC is considered a potential risk.

**Abbreviations:** MTC = medullary thyroid cancer.

### 5.3 Summary of safety concerns - Missing information

Risk	What is known
Women who want to become pregnant, are pregnant or are breastfeeding (Use in pregnant and lactating women)	Ozempic® has not been studied in pregnant women, women attempting to become pregnant or women who are breastfeeding. Ozempic® should not be used during pregnancy. It is not known if Ozempic® may harm the unborn child. It is not known if Ozempic® passes into breast milk, therefore Ozempic® should not be used when breastfeeding. The doctor should be informed if the patient is planning to become pregnant, there is suspicion of pregnancy or if the patient has become pregnant.

Less than 18 years old (Use in children and adolescents)	Ozempic® has not been studied in patients under 18 years. This means Ozempic® cannot currently be recommended for use in this age group.
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## 6 Summary of additional risk minimisation measures by safety concern

There are no additional measures put in place to address safety concerns

### 6.1 Planned post-authorisation development plan

Study/activity Type, title and category (1–3)	Objectives	Safety concerns addressed	Status (planned or started)	Date for submission of interim or final reports (planned or actual)
<b>MTC registry MTC- 22341 Category 3</b>	A medullary thyroid cancer case series registry to systematically monitor the annual incidence of medullary thyroid carcinoma in the US and to identify any increase related to the introduction of semaglutide into the marketplace	Medullary thyroid cancer	Ongoing	Final report TBD

MTC = medullary thyroid cancer.

Studies which are a condition of the marketing authorisation

Not applicable.

### 6.2 Summary of changes to the risk management plan over time

This is the first RMP to be submitted

This summary was last updated in Aug-2018.