



An Roinn Sláinte  
Department of Health

## Availability of semaglutide (Ozempic®)

### Important information for Healthcare Professionals and Patients

01 September 2023

Dear Healthcare Professional,

This information is issued with agreement from the Department of Health, Health Products Regulatory Authority (HPRA), Pharmaceutical Society of Ireland (PSI – the pharmacy regulator), Medical Council and various partners across the Health Service Executive (HSE). All parties are committed to working collaboratively on medicine shortages as part of the broader healthcare system to ensure that the appropriate information and guidance regarding medicines shortages is available.

The information provided is intended to supplement any related correspondence issuing from Novo Nordisk in relation to this matter. Key messages are as follows:

- Semaglutide (Ozempic®) is a glucagon-like peptide-1 (GLP-1) receptor agonist licensed for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise.
- As previously advised, an EU-wide supply constraint of semaglutide (Ozempic®), due to significant increased global demand, is ongoing and is expected to continue throughout 2023 and into 2024.
- Production issues in recent weeks at a manufacturing site will lead to a reduction in the overall supply of the 1mg strength to Ireland and other EU markets during the month of September. A potential further brief (approximately one week) constraint on the 0.5mg strength is anticipated in early October.
- Novo Nordisk has confirmed that these production issues are now resolved. It is expected that supply of the 1mg strength to Ireland will return to standard 2023 levels from October but the overall supply constraint will continue into 2024.
- Given the additional constraints on supply expected during September, priority should be given to continuing the treatment of such patients already commenced on Ozempic® particularly those for whom alternative treatments may not be suitable.
- Monthly allocations have been implemented at wholesale level to help ensure continuity of supply and equitable distribution of stock to patients. Pharmacies should not order extra quantities of Ozempic® over and above immediate patient need as doing so could exacerbate the supply constraints.

- To assist in the management of this product shortage, prescribing and dispensing should be prioritised for the licensed indication and restricted to a one-month supply.
- Healthcare professionals are requested to ensure that patients prescribed Ozempic® are made aware of this issue and to consider the most suitable course of action for the individual including whether a patient can be safely prescribed a clinically appropriate alternative, if required. Where possible, no new patients should be initiated on Ozempic® during September.
- A number of authorised alternative medicines indicated for treating adults with insufficiently controlled type 2 diabetes mellitus are available at this time, including other glucagon-like peptide (GLP-1) receptor agonists. Where this shortage impacts ongoing treatment for a patient, prescribers and pharmacists, in conjunction with patients, should discuss the most appropriate course of action, based on suitable alternative treatment options available.
- Reimbursement support for Ozempic® from the HSE is available for the licensed indication and approved dosage only.
- Reimbursement support for the 0.25 mg and 0.5 mg pen presentations of Ozempic® to make up a 1mg dose is not approved under Community Drug Schemes or any other HSE arrangement.
- National supply at wholesale level for all medicines in this class will continue to be monitored closely.
- The HSE National Clinical Programme for Diabetes is preparing clinical guidance.
- Novo Nordisk and wholesalers will continue to provide updates on the supply situation to, the HPRA and the HSE and further communications will be issued to keep healthcare professionals and patients informed.
- In addition, the GLP-1 receptor agonist, liraglutide (Saxenda®), is an authorised medicine marketed in Ireland that is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients. Prescribers can apply for reimbursement approval for suitable patients through the PCRS online application system ([www.pcrs.ie](http://www.pcrs.ie)).

## **Advice for patients**

### **I have been prescribed Ozempic®, what does this shortage mean for me?**

There is an ongoing shortage in the availability of Ozempic® across Europe. This situation is due to very high global demand. As there is now an additional shortage of supplies for September, you may find that your pharmacist does not have Ozempic® in stock or they may inform you that they have a limited supply. If this happens, your doctor or pharmacist can assist.

Your doctor may decide to prescribe you an alternative or similar medication.

### **I have been prescribed Ozempic® and I am due to start it soon, how will I be impacted?**

Your doctor may decide to start you on Ozempic in October rather than September if they deem this clinically safe. Your doctor may also suggest an alternative similar medication.

### **Why is there a shortage of Ozempic®?**

From time to time there can be shortages of certain medicines. This can happen for a number of reasons. For example, increased and unexpected demand, or a production delay.

With Ozempic®, there is an ongoing global shortage due to a greater demand than expected. The company that produces Ozempic®, Novo Nordisk, is working on increasing its capacity to produce more.

There is now an increased shortage in deliveries for the month of September for one strength of Ozempic® and a delay of one week in October for another strength. This is due to a production delay.

If your medicine is unavailable, your pharmacist can advise you based on your prescription.

### **When will the shortages be resolved?**

The manufacturer has confirmed that the issues relating to the September shortages have now been addressed. Standard 2023 levels of deliveries are expected to return to Ireland at the start of October.

The pre-existing global supply challenges will continue for some time as the manufacturer continues to increase its capacity to produce more.

### **What is being done to address the shortages?**

The HPRA, the HSE, the Pharmaceutical Society of Ireland (PSI) and the Department of Health are working together with clinical experts and other stakeholders to provide appropriate information and guidance regarding medicines shortages.

The company that produces Ozempic®, Novo Nordisk, is working on increasing its capacity to produce more.

The HPRA is engaging closely with the company and the wholesalers involved in the supply of this product. This is to closely monitor available stock and to keep the health system and the public informed.

### **Should I source my Ozempic® online instead?**

The online supply of prescription medicines, such as Ozempic®, is illegal in Ireland.

You should only obtain Ozempic® through recognised and regulated sources, such as your local pharmacy. This way you know you are getting a medicine that contains the right ingredients and that is tailored to your specific needs under the supervision of a doctor or pharmacist.