Semaglutide (Ozempic®)

Prescribing Information Sheet, November 2020

This document provides general prescribing information on the use of Semaglutide. For the most up to date information, consult the summary of product characteristics.

For information on Bedfordshire and Luton Joint Prescribing Committee (JPC) recommendations on place in therapy, prescribing and monitoring requirements and responsibilities, please consult the 'Overarching Shared Care Guideline for the use of Glucagon-like peptide 1 (GLP 1) agonists.' Document.

Licensed Indication	Semaglutide is indicated 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 • in addition to other medicinal products for the treatment of diabetes. For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see the SPC
Drug dose	**Adult patients 18 years and over:-** The starting dose is 0.25 mg semaglutide 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. Semaglutide 0.25 mg is not a maintenance dose. Weekly doses higher than 1 mg are not recommended.
Dose modifications in Special Populations	**Elderly** • No dose adjustment is required based on age. Therapeutic experience in patients ≥75 years of age is limited. **Renal Impairment** • No dose adjustment is required for patients with mild, moderate or severe renal impairment. Experience with the use of semaglutide in patients with severe renal impairment is limited. Semaglutide is not recommended for use in patients with end-stage renal disease. **Hepatic Impairment** • No dose adjustment is required for patients with hepatic impairment. Experience with the use of Semaglutide in patients with severe hepatic impairment is limited. Caution should be exercised when treating these patients with semaglutide. **Added to other hypoglycaemic agents**

	When Semaglutide is added to existing metformin and/or thiazolidinedione therapy, the current dose of metformin and/or thiazolidinedione can be continued unchanged. When Semaglutide is added to existing therapy of sulfonylurea or insulin, a reduction in the dose of sulfonylurea or insulin should be considered to reduce the risk of hypoglycaemia. Self-monitoring of blood glucose is not needed in order to adjust the dose of semaglutide. Blood glucose self-monitoring is necessary to adjust the dose of sulfonylurea and insulin, particularly when semaglutide is started and insulin is reduced. A stepwise approach to insulin reduction is recommended.
Administration details	• Semaglutide is to be injected subcutaneously in the abdomen, thigh or upper arm. • It should not be administered intravenously or intramuscularly. • The dose can be administered (once weekly) at any time of day, with or without meals. • If a dose is missed, it should be administered as soon as possible and within 5 days after the missed dose. If more than 5 days have passed, the missed dose should be skipped, and the next dose should be administered on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule. • The day of weekly administration can be changed if necessary as long as the time between two doses is at least 3 days (>72 hours). After selecting a new dosing day, once-weekly dosing should be continued.
Formulations	0.25mg/0.19ml solution for injection 1.5ml pre-filled pen; 0.5mg/0.37ml solution for injection 1.5ml pre-filled pen; 1mg/0.74ml solution for injection 3ml pre-filled pen.
Duration of Action	Semaglutide has a prolonged half-life of around a week making it suitable for once weekly subcutaneous administration.
Contra-indications / Cautions	Clinicians should refer to the Summary of Product Characteristics (SPC's) or the current electronic BNF for full details **Contra-indications** Semaglutide is contra-indicated in patients who have experienced hypersensitivity to the active substance or to any of the excipients; diabetic ketoacidosis; severe congestive heart failure. **Cautions** Semaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Semaglutide is not a substitute for insulin. Diabetic ketoacidosis has been reported in insulin-dependent patients whom had rapid discontinuation or dose reduction of insulin when treatment with a GLP-1 receptor agonist is started Use of GLP-1 receptor agonists may be associated with gastrointestinal adverse reactions. This should be considered when treating patients, with impaired renal function as nausea, vomiting, and diarrhoea may cause dehydration which could cause a deterioration of renal function.

	Acute pancreatitis has been observed with the use of GLP-1 receptor agonists. **Patients should be informed of the characteristic symptoms of acute pancreatitis**. If pancreatitis is suspected, semaglutide should be discontinued; if confirmed, semaglutide should not be restarted. Caution should be exercised in patients with a history of pancreatitis. In patients with diabetic retinopathy treated with insulin and semaglutide, an increased risk of developing diabetic retinopathy complications has been observed. Caution should be exercised when using semaglutide in patients with diabetic retinopathy treated with insulin. These patients should be monitored closely and treated according to clinical guidelines.
Side effects	Clinicians should refer to the Summary of Product Characteristics (SPC) and current electronic BNF for full details Semaglutide is denoted as a black triangle (▼) drug. Report all side effects using the yellow card scheme A list of very common/common side effects include: • Hypoglycaemia when used with insulin or sulfonylurea • Nausea • Diarrhoea • Hypoglycaemiaa when used with other OADs • Dizziness • Diabetic retinopathy complications • Vomiting • Abdominal pain • Abdominal distension • Constipation • Dyspepsia • Gastritis • Gastro-oesophageal reflux disease • Eructation • Flatulence • Cholelithiasis • Fatigue • Increased lipase • Increased amylase • Weight decreased • Decreased appetite **MHRA warning (June 2019)** – GLP-1 receptor agonists: reports of diabetic ketoacidosis when concomitant insulin was rapidly reduced or discontinued. Semaglutide was not subject to the EU review. At the time of publication of the MHRA warning, no UK reports of diabetic ketoacidosis in association with semaglutide has been received. However, the theoretical risk of ketoacidosis when changes are made to insulin dose cannot be excluded.

Drug Interactions	Semaglutide delays gastric emptying and has the potential to impact the rate of absorption of concomitantly administered oral medicinal products. Semaglutide should be used with caution in patients receiving oral medicinal products that require rapid gastrointestinal absorption. Clinicians should check the Summary of Product Characteristics (SPC) and the current electronic BNF for a full list of potential drug interactions before starting any new medication or when stopping any existing medication.
Alcohol	There is no specific interaction between semaglutide and alcohol, however, for general health reasons it recommended that both men and women should drink no more than 14 units / week and they should also have at least two alcohol-free days during the week.
Pregnancy and Breastfeeding	Women of childbearing potential are recommended to use contraception when treated with semaglutide. Studies in animals have shown reproductive toxicity. There are limited data from the use of semaglutide in pregnant women. Therefore, semaglutide should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, semaglutide should be discontinued. Semaglutide should be discontinued at least 2 months before a planned pregnancy due to the long half-life. In lactating rats, semaglutide was excreted in milk. As a risk to a breast-fed child cannot be excluded, semaglutide should not be used during breast-feeding.
Effects on ability to drive and use machines	Semaglutide has no or negligible influence on the ability to drive or use machines. When it is used in combination with a sulfonylurea or insulin, patients should be advised to take precautions to avoid hypoglycaemia while driving and using machines.
Storage Conditions	It is initially necessary to refrigerate semaglutide (2 °C – 8 °C) but once in use, it may be stored unrefrigerated for up to 6 weeks below 30 °C. Keep the pen cap on in order to protect from light Do not freeze

References:-

1. Summary of Product Characteristics for Ozempic® (Semaglutide), accessed 29/10/20
2. eBNF, accessed 29/10/20
3. Drug Safety Update, MHRA, June 2019