

Generic: semaglutide (FDA approved 12/05/2017)

Company: Novo Nordisk

Agent for: Type 2 Diabetes Mellitus (T2DM)

Indications: Adjunct to diet and exercise to improve glycemic control in adults with T2DM

Mechanism of Action: Semaglutide is a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor. Insulin secretion is stimulated and glucagon secretion is lowered in a glucose-dependent manner. The long half-life of semaglutide is a result of the product binding to albumin.

COMPARABLE DRUG: Liraglutide (Victoza, Saxenda), lixisenatide (Lyxumia, Adlyxin), dulaglutide (Trulicity), exenatide (Byetta/Bydureon)

COST PER MONTH (WAC)

OZEMPIC (2 MG/ 1.5 ML): \$676.00

VICTOZA (1.8 MG/ 3 ML): \$806.67

SAXENDA (18 MG/3 ML): \$1,154.25

ADLYXIN (100 MCG/ ML): \$557.20

TRULICITY (1.5MG/ 0.5ML): \$676.00

BYETTA (250MCG/ ML): \$708.38

BYDUREON (2MG): \$660.16

ADVANTAGES:

- Treatment is a once weekly injection which may increase adherence
- Has been shown to be more effective than Trulicity in reducing blood sugar in clinical trials
- Statistically significant reductions in weight loss were seen during clinical trials

DISADVANTAGES:

- Not recommended as first line therapy
- In clinical trials, a slightly higher rate of eye damage was observed

MOST IMPORTANT RISKS/ADVERSE EVENTS: Most severe adverse risks include pancreatitis and risk of thyroid C-cell tumors, which were seen in mice and rats. However, the relevance in humans of semaglutide-induced rodent thyroid C-cell tumors have not been determined.

MOST COMMON ADVERSE EVENTS: Common side effects include nausea, vomiting, diarrhea, abdominal pain, and constipation.

USUAL DOSAGE: Ozempic is administered as a subcutaneous injection in the abdomen, thigh or upper arm once weekly on the same day, at any time, with or without food. Patients will begin with 0.25 mg injections and increase the dose to 0.5 mg after 4 weeks. If additional glycemic control is needed after 4 weeks on a 0.5 mg dose, dose is increased to 1mg.

PRODUCT: The product is a clear, colorless solution (2 mg/1.5 mL) in a pre-filled, disposable, single-patient-use pen injector. There are two different pens that dispense 0.25 mg/ 0.5 mg per injection or 1 mg per injection. Prior to first use, product should be stored in a refrigerator (36°F to 46°F). After first use, it can be kept at room temperature (59°F to 86°F) for 56 days or refrigerated. A new needle should be used for each injection.

COMMENTS: Diabetes is one of the biggest health challenges in the US and is projected to affect 33% of Americans by 2050. There are two types of diabetes. Type 1 diabetes is a chronic condition where the pancreas cannot produce enough insulin. Type 2 diabetes is a chronic condition that affects the way the body processes blood sugar. Type 2 diabetes is characterized by elevated levels of blood glucose and is associated with morbidity and mortality. Current treatments include diet and exercise, and medications that aim to bring blood sugar levels back to normal by increasing insulin production or decreasing sugar absorption. Generally metformin is the first medication prescribed. Additional medications are added to the regime if glycemic control is not obtained. In clinical trials, patients taking semaglutide had clinically and statistically significant reductions in HbA1c levels compared with placebo, sitagliptin, exenatide ER, and insulin glargine U100. A pill version of Ozempic is also in the clinical trial phase, which may be the first GLP-1 receptor agonist that does not require an injection.