POTENZA®

Semaglutide INN

Composition

POTENZA® Solution for SC Injection: Each ml solution contains Semaglutide INN 1.34 mg.

Pharmacology

POTENZA® (Semaglutide) is a GLP-1 analogue which acts as a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor, the target for native GLP-1. **POTENZA**® reduces blood glucose through a mechanism where it stimulates insulin secretion and lowers glucagon secretion, both in a glucose-dependent manner. The mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase.

Indication

POTENZA® is indicated:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- 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.

Limitations of use:

- It has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- It is not indicated for use in patients with type 1 diabetes mellitus.

Dose and administration

Route of administration: **POTENZA**® should be administered as a subcutaneous injection.

Instructions for patient

Before injecting the solution:

1. According to instruction given with **Biopen *flexi*** pen device, insert the **POTENZA**® cartridge into the pen correctly, equip the needle and let the cartridge reach room temperature before using it.
2. Remove the needle cap and discharge air bubbles in cartridge.
3. Adjust the dosage button to get correct dose and inject to the specific site.
4. In order to avoid cross contamination, do not let the needle touch anything during the process of preparation.

To be used only with **Biopen *flexi*** pen device. For detail description, please see the Patient Instruction Leaflet provided with **Biopen *flexi*** pen device.

Dosage instruction

- Start with a 0.25 mg subcutaneous injection once weekly for 4 weeks. The 0.25 mg dosage is intended for treatment initiation and is not effective for glycemic control.
- After 4 weeks on the 0.25 mg dosage, increase the dosage to 0.5 mg once weekly. If additional glycemic control is needed after at least 4 weeks on the 0.5 mg dosage, the dosage may be increased to 1 mg once weekly. If additional glycemic control is needed after at least 4 weeks on the 1 mg dosage, the dosage may be increased to 2 mg once weekly. The maximum recommended dosage is 2 mg once weekly.
- Administer the product once weekly, on the same day each week, at any time of the day, with or without meals. 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).
- If a dose is missed, administer it as soon as possible within 5 days after the missed dose. If more than 5 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.

Administration

- Administer it subcutaneously to the abdomen, thigh or upper arm. Instruct patients to use a different injection site each week when injecting in the same body region.
- Inspect it visually before use. It should appear clear and colorless. Do not use if particulate matter and coloration is seen.
- When using with insulin, instruct patients to administer as separate injections and to never mix the products. It is acceptable to inject **POTENZA**® and insulin in the same body region but the injections should not be adjacent to each other.

Contraindication

Semaglutide is contraindicated in patients with known hypersensitivity to semaglutide or any other components of this product. It is also contraindicated in a personal or family history of medullary thyroid carcinoma (MTC) or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2).

Warning and precaution

Counsel patients regarding the potential risk for MTC with the use of semaglutide and inform them of symptoms of thyroid tumors. After initiation of treatment, observe patients carefully for signs and symptoms of pancreatitis. If pancreatitis is suspected, it should be discontinued and appropriate management should be initiated. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy. This **Biopen *flexi*** pen device must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin. Monitor renal function when initiating or escalating doses in patients reporting severe adverse gastrointestinal reactions. If hypersensitivity reactions occur, discontinue it; treat promptly per standard of care and monitor until signs and symptoms resolve. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

Side effects

The most common side effects are nausea, vomiting, diarrhea, abdominal pain and constipation.

Use in pregnancy and lactation

Pregnancy: There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy. Semaglutide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need and any potential adverse effects on the breastfed infant from semaglutide or from the underlying maternal condition.

Use in children and adolescents

Safety and efficacy of semaglutide have not been established in patients younger than 18 years.

Drug interaction

Drug interaction with medication: When initiating semaglutide, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia. Semaglutide causes a delay of gastric emptying and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with semaglutide.

Drug interaction with food and others: Not applicable.

Overdose

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 semaglutide of approximately 1 week.

Storage

Keep out of the reach and sight of children. Store in a refrigerator at 2ºC to 8ºC. After first use of the product, the pen can be stored for 56 days in a refrigerator at 2ºC to 8ºC. Do not freeze and protect from light. Do not use if it has been frozen. To be taken and sold only on the prescription of a registered physician.

Packing

POTENZA® Solution for SC Injection: Each box contains 1 cartridge of 3 ml.

® Registered Trade Mark

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