Reglutide®

Semaglutide
Solution for Subcutaneous Injection

Description

Reglutide®, a preparation of Semaglutide injection for subcutaneous use, is a human GLP-1receptor agonist (or GLP-1 analog). Reglutide® is a sterile, aqueous, clear and colorless solution.

Pharmacology

Semaglutide is a GLP-1 analogue with 94% sequence homology to human GLP-1. Semaglutide acts as a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor. GLP-1 is a physiological hormone that has multiple actions on glucose, mediated by the GLP-1 receptors. Semaglutide reduces blood glucose through a mechanism where it stimulates insulin secretion and lowers glucagon secretion, both in a glucose-dependent manner.

Indications

Reglutide® is a glucagon-like peptide 1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

Dosage and Administrations

Start at 0.25 mg (please set 19 units on the pen dialer) once weekly. After 4 weeks, increase the dose to 0.5 mg (please set 37 units on the pen dialer) once weekly. If after at least 4 weeks additional glycemic control is needed, increase to 1 mg once weekly. Administer once weekly at any time of day, with or without meals. If a dose is missed administer within 5 days of missed dose. Inject subcutaneously in the abdomen, thigh, or upper arm.

Contraindications

Semaglutide is contraindicated in patients with personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) and hypersensitivity to Semaglutide. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with Semaglutide.

Warning and Precautions

Risk of Thyroid C-Cell Tumors

It is unknown whether Reglutide® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans.

Pancreatitis

After initiation of Reglutide®, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, Reglutide® should be discontinued and appropriate management initiated; if confirmed, Reglutide® should not be restarted.

Diabetic Retinopathy Complications

The effect of long-term glycemic control with Semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

Never Share Reglutide Pen Between Patients

Reglutide® pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens.

Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin Patients receiving Reglutide® in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin.

Acute Kidney Injury

There have been post-marketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists.

Hypersensitivity

Do not use in patients with a previous hypersensitivity to Semaglutide. If hypersensitivity reactions occur, discontinue use of Semaglutide; treat promptly per standard of care, and monitor until signs and symptoms resolve.

Side Effects

It is not known if Reglutide® will cause thyroid tumors or medullary thyroid carcinoma (MTC) in people. Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath.

Use in Specific Populations

Pregnancy

There are limited data with Semaglutide use in pregnant women. Reglutide® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

There are no data on the presence of Semaglutide in human milk, the effects on the breastfed infant, or the effects on milk production.

Females and Males of Reproductive Potential

Discontinue Reglutide® in women at least 2 months before a planned pregnancy due to the long washout period for Semaglutide.

Pediatric Use

Safety and efficacy of Reglutide® have not been established in pediatric patients (younger than 18 years).

Geriatric Use

No overall differences in safety or efficacy were detected between geriatric patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment

No dose adjustment of Reglutide® is recommended for patients with renal impairment.

Hepatic Impairment

No dose adjustment of Reglutide® is recommended for patients with hepatic impairment.

Drug interactions

Initiating Reglutide® concomitant with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia. In clinical pharmacology trials, Semaglutide did not affect the absorption of orally administered medications to any clinically relevant degree. Nonetheless, caution should be exercised when oral medications are concomitantly administered with Reglutide®.

Overdose

In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms.

Pharmaceutical Precautions

Recommended Storage

- Store your Reglutide® in the refrigerator at 2°C to 8°C.
- After first use of the Reglutide®, the pen can be stored for 56 days in a refrigerator (2°C to 8°C).
- Do not freeze Reglutide®. Do not use Reglutide® if it has been frozen.
- Unused Reglutide® cartridge may be used until the expiration date printed on the label, if kept in the refrigerator (2°C to 8°C).
- Keep Reglutide® away from heat and out of the light.
- Keep the pen cap on when not in use.

Commercial Pack

Reglutide® Injection: Box containing 3 ml cartridge of Reglutide®. Each 1 ml contains 1.34 mg of Semaglutide INN.

BEXIMCO PHARMA

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