

390 mm

124 mm

124 mm

60 mm



RxSemaglutide Injection
ডায়নাসেমো
DYNASEMO®
Semaglutide Injection Prefilled Pen

Note:
Always use the dose counter and the dose pointer to see required dose. You will hear a “click” every time you turn the dose selector. Do not set the dose by counting the number of clicks you hear.
Only required dose can be selected with the dose selector. Selected dose must line up exactly with the dose pointer to make sure that you get a correct dose.
The dose selector changes the dose. Only the dose counter and dose pointer will show that required dose has been selected. The dose selector clicks differently when turned forward or backward. Do not count the pen clicks.

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How much Semaglutide is left?

• To see how much Semaglutide is left in your pen, use the dose counter:
Turn the dose selector until the dose counter stops.

• If it shows 1, at least 1 mg is left in your pen. If the dose counter stops before 1 mg, there is not enough Semaglutide left for a full dose of 1 mg.
If there is not enough Semaglutide left in your pen for a full dose, do not use it. Use a new Semaglutide pen.

Step 4. Inject your dose

• Choose your injection site and wipe the skin with an alcohol swab. Let the injection site dry before you inject your dose

• Insert the needle into your skin as your healthcare provider has shown you.

• Make sure you can see the dose counter. Do not cover it with your fingers. This could stop the injection.

• Press and hold down the dose button until the dose counter shows 0. The 0 must line up with the dose pointer. You may then hear or feel a click. Continue pressing the dose button while keeping the needle in your skin.

• Count 6 seconds while keeping the dose button pressed.
• If the needle is removed earlier, you may see a stream of Semaglutide coming from the needle tip. If this happens, the full dose will not be delivered.

• Remove the needle from your skin. You can then release the dose button. If blood appears at the injection site, press lightly with a gauze pad or cotton ball.
Do not rub the area.

Note:
Always watch the dose counter to make sure you have injected your complete dose. Hold the dose button down until the dose counter shows 0. How to identify a blocked or damaged needle?
• If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.
• If this happens you have not received any Semaglutide even though the dose pointer has moved from the original dose that you have set.
• How to handle a blocked needle?
Change the needle as described in Step 5, and repeat all steps starting with Step 1: “Prepare your pen with a new needle”.
Never touch the dose counter when you inject. This can stop the injection.
You may see a drop of Semaglutide at the needle tip after injecting. This is normal and does not affect your dose.

Step 5. After your injection

• Carefully remove the needle from the pen. Do not put the needle caps back on the needle to avoid needle sticks.

• Place the needle in a sharps disposal container right away to reduce the risk of needle sticks. See “Disposing of used pens and needles” below for more information about how to dispose of used pens and needles the right way.

• Put the pen cap on your pen after each use to protect Semaglutide from light.

• If you do not have a sharps disposal container, follow a 1-handed needle recapping method. Carefully slip the needle into the outer needle cap. Dispose of the needle in a sharps disposal container as soon as possible.

Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

Always remove the needle from your pen. This will reduce the risk of contamination, infection, leakage of Semaglutide, and blocked needles leading to the wrong dose. If the needle is blocked, you will not inject any Semaglutide.

Always dispose of the needle after each injection.

Disposing of used Semaglutide pens and needles:

- Put your used Semaglutide pen and needle in a disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant or properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes.
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.
- Safely dispose of Semaglutide that is out of date or no longer needed.

Important:

- Caregivers must be very careful when handling used needles to prevent accidental needle stick injuries and prevent passing (transmission) of infection.
- Never use a syringe to withdraw Semaglutide from your pen.
- Always carry an extra pen and new needles with you, in case of loss or damage.
- Always keep your pen and needles out of reach of others, especially children.
- Always keep your pen with you. Do not leave it in a car or other place where it can get too hot or too cold.

Caring for your pen:

- Do not drop your pen or knock it against hard surfaces. If you drop it or suspect a problem, attach a new needle and check the Semaglutide flow before you inject.
- Do not try to repair your pen or pull it apart.
- Do not expose your pen to dust, dirt or liquid.
- Do not wash, soak, or lubricate your pen. If necessary, clean it with mild detergent on a moistened cloth.
- How should I store my Semaglutide pen?
- Store your new, unused Semaglutide pens in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Store your pen in use for 56 days at room temperature between 59°F to 86°F (15°C to 30°C) or in a refrigerator between 36°F to 46°F (2°C to 8°C).
- The Semaglutide pen you are using should be disposed of (thrown away) after 56 days, even if it still has Semaglutide left in it. Write the disposal date on your calendar.
- Do not freeze Semaglutide. Do not use Semaglutide if it has been frozen.
- Unused Semaglutide pens may be used until the expiration date (“EXP”) printed on the label, if kept in the refrigerator.
- When stored in the refrigerator, do not store Semaglutide pens directly next to the cooling element.
- Keep Semaglutide away from heat and out of the light.
- Keep the pen cap on when not in use.
- Keep Semaglutide and all medicines out of the reach of children.

Brief Information about How to use Semaglutide Prefilled Pen

1. Prepare the Injection Pen:

- Semaglutide is typically provided in a pre-filled injection pen, similar to other injectable medications like insulin.
- Wash your hands thoroughly.
- Attach a new needle to the pen, if necessary.
- Remove the protective cap from both the needle and the pen.

2. Prime the Pen:

- Hold the pen with the needle pointing upward.
- Turn the dose selector to a small dose (usually 0.25 mg/0.5 mg/1mg/1.7 mg/2.4 mg depending on the prescription) to ensure the pen is primed and ready to administer the medication.

3. Choose the Injection Site:

- The recommended areas for injection are the stomach, thigh, or upper arm.
- Clean the skin with an alcohol swab.

4. Inject the Medication:

- Pinch the skin to create a fold and insert the needle at a 90-degree angle.
- Press the injection button to administer the dose.
- Hold the needle in place for a few seconds to ensure all the medication is delivered.

5. Dispose of the Needle:

- Remove the needle and dispose of it in a proper sharps container.
- Replace the cap on the pen for storage.

To Report Suspected Adverse Reaction, Contact Bharat Serums and Vaccines Ltd. at pv@bsvgroup.com or visit the website <https://www.bsvgroup.com/adverse/>

To be sold by retail on the prescription of Gastroenterologist only

PRSCRIBING INFORMATION
SEMAGLUTIDE INJECTION
1MG/1.5ML, 2MG/1.5ML, 4MG/3ML, 6.8MG/3ML, 9.6MG/3ML

WARNINGS: RISK OF THYROID C-CELL TUMORS
In rodents, Semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Semaglutide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of Semaglutide-induced rodent thyroid C-cell tumors has not been determined.
• Semaglutide is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Semaglutide and inform them of symptoms of thyroid tumors.

1. Generic Name:
Semaglutide Injection 1mg/1.5mL, 2mg/1.5mL, 4mg/3mL, 6.8 mg/3mL, 9.6mg/3mL.

2. Qualitative and Quantitative Composition:
Each prefilled pen contains a 1.5 mL solution of Semaglutide injection is equivalent to 1 mg Semaglutide (0.68 mg/mL).
Each prefilled pen contains a 3 mL solution of Semaglutide injection is equivalent to 2 mg Semaglutide (1.34mg/mL).
Each prefilled pen contains a 3mL solution of Semaglutide injection is equivalent to 4 mg Semaglutide (1.34mg/mL).
Each prefilled pen contains a 3 mL solution of Semaglutide injection is equivalent to 6.8 mg Semaglutide (2.27mg/mL).
Each prefilled pen contains a 3mL solution of Semaglutide injection is equivalent to 9.6 mg Semaglutide (3.2mg/mL).

3. Dosage Form & Strength:
Injection; clear, colorless solution available in pre-filled, disposable, single-dose pens at strengths 1mg/1.5mL, 2mg/1.5mL, 4mg/3mL, 6.8mg/3mL, 9.6mg/3mL.

4. Clinical Particulars:
4.1 Therapeutic Indications
It is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:
• 30 kg/m² or greater (obesity) or
• 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).

4.2 Posology and Method of administration:
Important Monitoring and Administration Instructions
• In patients with type 2 diabetes, monitor blood glucose prior to starting Semaglutide and during Semaglutide treatment.
• Prior to initiation of Semaglutide, train patients on proper injection technique. Refer to the accompanying Instructions for Use for detailed instructions.
• Administer Semaglutide visually prior to each injection. Only use if solution is clear, colorless, and contains no particles.
• Administer Semaglutide in combination with a reduced-calorie diet and increased physical activity.
• Administer Semaglutide once weekly, on the same day each week, at any time of day, with or without meals.
• Inject Semaglutide subcutaneously in the abdomen, thigh, or upper arm. The time of day and the injection site can be changed without dose adjustment.

Recommended Dosage in Adults:
Dosage Initiation and Escalation:
• Initiate Semaglutide with a dosage of 0.25 mg injected subcutaneously once weekly. Then follow the dose escalation schedule presented in Table 1 to minimize gastrointestinal adverse reactions.
• If patients do not tolerate a dose during dosage escalation, consider delaying dosage escalation for 4 weeks.

Table: 1 Recommended Dosage Regimen for Adults:

Treatment	Weeks	Once weekly Subcutaneous Dosage
Initiation	1 through 4	0.25 mg
Escalation	5 through 8	0.5 mg
	9 through 12	1 mg
	13 through 16	1.7 mg
Maintenance	17 and onward	1.7 mg or 2.4 mg

Maintenance Dosage:
The maintenance dosage of Semaglutide in adults is either 2.4 mg (recommended) or 1.7 mg once weekly. Consider treatment response and tolerability when selecting the maintenance dosage.

Dosage Modifications for Adverse Reactions:
• If patients do not tolerate the 2.4 mg once-weekly maintenance dosage, the maintenance dosage may be reduced to 1.7 mg once-weekly.
• Discontinue Semaglutide if the patient cannot tolerate the 1.7 mg once-weekly dosage.

Recommendations Regarding Missed Dose:
• If one dose is missed and the next scheduled dose is more than 2 days away (48 hours), administer Semaglutide as soon as possible. If one dose is missed and the next scheduled dose is less than 2 days away (48 hours), do not administer the dose. Resume dosing on the regularly scheduled day of the week.

• If 2 or more consecutive doses are missed, resume dosing as scheduled or, if needed, reinstate Semaglutide and follow the dose escalation schedule, which may reduce the occurrence of gastrointestinal symptoms associated with re-initiation of treatment.

Special Patient Populations:
Renal Impairment:
No dose adjustment of semaglutide is recommended for patients with renal impairment. In a study in patients with renal impairment, including end-stage renal disease, no clinically relevant change in semaglutide pharmacokinetics was observed.
Hepatic Impairment:
No dose adjustment of semaglutide is recommended for patients with hepatic impairment. In a study in patients with different degrees of hepatic impairment, no clinically relevant change in semaglutide pharmacokinetics was observed.

4.3 Contraindications:
Semaglutide is contraindicated in patients with:
• A personal or family history of MTC or in patients with MEN 2
• A prior serious hypersensitivity reaction to Semaglutide or to any of the excipients in Semaglutide. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with Semaglutide.

4.4 Special warnings and precautions for use
Risk of Thyroid C-Cell Tumors:
In mice and rats, semaglutide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure at clinically relevant plasma exposures. It is unknown whether Semaglutide causes thyroid C-cell tumors, including MTC, in humans as human relevance of Semaglutide-induced rodent thyroid C-cell tumors has not been determined.
Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist, have been reported in the post marketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans.
Semaglutide is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of Semaglutide and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness).
Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Semaglutide. Such monitoring may increase the risk of unnecessary procedures, due to the low-test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin value may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

Acute Pancreatitis:
In mice and rats, semaglutide caused a dose-dependent and treatment-duration-dependent increase in the incidence of pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, including semaglutide. Acute pancreatitis was observed in patients treated with Semaglutide in clinical trials. After initiation of Semaglutide, observe patients carefully for signs and symptoms of acute pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back, and which may or may not be accompanied by vomiting). If acute pancreatitis is suspected, Semaglutide should promptly be discontinued, and appropriate management should be initiated. If acute pancreatitis is confirmed, Semaglutide should not be restarted.
There is limited experience from clinical trials with Semaglutide in patients with a history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for development of pancreatitis on Semaglutide.

Acute Gallbladder Disease:
Treatment with Semaglutide is associated with an increased occurrence of cholelithiasis and cholecystitis. The incidence of cholelithiasis and cholecystitis was higher in Semaglutide-treated pediatric patients aged 12 years and older than in Semaglutide-treated adults. In randomized clinical trials in adult patients, cholelithiasis was reported by 1.6% of Semaglutide-treated patients and 0.7% of placebo-treated patients. Cholecystitis was reported by 0.6% of Semaglutide-treated adult patients and 0.2% of placebo-treated patients. In a clinical trial in pediatric patients aged 12 years and older, cholelithiasis was reported by 3.8% of Semaglutide-treated patients and 0% placebo-treated patients. Cholecystitis was reported by 0.8% of Semaglutide-treated pediatric patients and 0% placebo-treated patients. Substantial or rapid weight loss can increase the risk of cholelithiasis; however, the incidence of acute gallbladder disease was greater in Semaglutide-treated patients than in placebo-treated patients, even after accounting for the degree of weight loss. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

Hypoglycemia:
Semaglutide lowers blood glucose and can cause hypoglycemia.
In a trial of adult patients with type 2 diabetes and body mass index (BMI) greater than or equal to 27 kg/m², hypoglycemia (defined as a plasma glucose less than 54 mg/dL) was reported in 6.2% of Semaglutide-treated patients versus 2.5% of placebo-treated patients. One episode of severe hypoglycemia (requiring the assistance of another person) was reported in one Semaglutide-treated patient versus no placebo-treated patients.
Patients with diabetes mellitus taking Semaglutide in combination with insulin or an insulin secretagogue (e.g., sulfonylurea) may have an increased risk of hypoglycemia, including severe hypoglycemia. Hypoglycemia has been observed in patients treated with semaglutide at doses of 0.5 and 1 mg in combination with insulin. The use of Semaglutide (semaglutide 2.4 mg or 1.7 mg once weekly) in patients with type 1 diabetes mellitus or in combination with insulin has not been evaluated.
Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia. In patients with diabetes, monitor blood glucose prior to starting Semaglutide and during Semaglutide treatment. When initiating Semaglutide, consider reducing the dose of concomitantly administered insulin or insulin secretagogue (such as sulfonylurea) to reduce the risk of hypoglycemia.

Acute Kidney Injury:
There have been post marketing reports of acute kidney injury and worsening of chronic renal failure, which have in some cases required hemodialysis, in patients treated with semaglutide. Patients with renal impairment may be at greater risk of acute kidney injury, but some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, or diarrhea, leading to volume depletion.
Monitor renal function when initiating or escalating doses of Semaglutide in patients reporting severe adverse gastrointestinal reactions. Monitor renal function in patients with renal impairment reporting any adverse reactions that could lead to volume depletion.

Hypersensitivity Reactions:
Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with Semaglutide. If hypersensitivity reactions occur, discontinue use of Semaglutide, treat promptly per standard of care, and monitor until signs and symptoms resolve. Semaglutide is contraindicated in patients with a prior serious hypersensitivity reaction to semaglutide or to any of the excipients in Semaglutide.
Anaphylaxis and angioedema have been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of anaphylaxis or angioedema with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to these reactions with Semaglutide.

Diabetic Retinopathy Complications in Patients with Type 2 Diabetes:
In a trial of adult patients with type 2 diabetes and BMI greater than or equal to 27 kg/m², diabetic retinopathy was reported by 4.0% of Semaglutide-treated patients and 2.7% placebo-treated patients.
In a 2-year trial with semaglutide 0.5 mg and 1 mg once-weekly injection in adult patients with type 2 diabetes and high cardiovascular risk, diabetic retinopathy complications (which was a 4-component adjudicated endpoint) occurred in patients treated with semaglutide injection (5.1%) compared to placebo (1.5%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline (semaglutide injection 8.2%, placebo 5.2%) than among patients without a known history of diabetic retinopathy (semaglutide injection 0.7%, placebo 0.4%).
Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. 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.

Heart Rate Increase:
Treatment with Semaglutide was associated with increases in resting heart rate. Mean increases in resting heart rate of 1 to 4 beats per minute (bpm) were observed in Semaglutide-treated adult patients compared to placebo in clinical trials. In adult patients treated with Semaglutide compared with placebo had maximum changes from baseline at any visit of 10 to 19 bpm (41% versus 34%, respectively) and 20 bpm or more (26% versus 16%, respectively). In a clinical trial in pediatric patients aged 12 years and older with normal baseline heart rate, more patients treated with Semaglutide compared to placebo had maximum changes in heart rate of 20 bpm or more (54% versus 39%).
Monitor heart rate at regular intervals consistent with usual clinical practice. Instruct patients to inform their healthcare providers of palpitations or feelings of a racing heartbeat while at rest during Semaglutide treatment. If patients experience a sustained increase in resting heart rate, discontinue Semaglutide.

Pulmonary Aspiration During General Anesthesia or Deep Sedation:
Semaglutide delays gastric emptying. There have been rare post marketing reports of pulmonary aspiration in patients receiving GLP-1 receptor agonists undergoing elective surgeries or procedures requiring general anesthesia or deep sedation who had residual gastric contents despite reported adherence to preoperative fasting recommendations.
Available data are insufficient to inform recommendations to mitigate the risk of pulmonary aspiration during general anesthesia or deep sedation in patients taking Semaglutide, including whether modifying preoperative fasting recommendations or temporarily discontinuing Semaglutide could reduce the incidence of retained gastric contents. Instruct patients to inform healthcare providers prior to any planned surgeries or procedures if they are taking Semaglutide.

4.4 Interactions
Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin:
Semaglutide lowers blood glucose and can cause hypoglycemia. The risk of hypoglycemia is increased when Semaglutide is used in combination with insulin or insulin secretagogues (e.g., sulfonylureas). The addition of Semaglutide in patients treated with insulin has not been evaluated. When initiating Semaglutide, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylurea) or insulin to reduce the risk of hypoglycemia.

Oral Medications:
Semaglutide causes a delay of gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. In clinical pharmacology trials, Semaglutide did not affect the absorption of orally administered medications. Nonetheless, monitor the effects of oral medications concomitantly administered with Semaglutide.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients, etc.)
Pregnancy:
When a pregnancy is recognized, advise the pregnant patient of the risk to a fetus, and discontinue Semaglutide.

Lactation:
There are no data on the presence of semaglutide or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Semaglutide and any potential adverse effects on the breastfed infant from Semaglutide or from the underlying maternal condition.

Females and Males of Reproductive Potential:
Because of the potential for fetal harm, discontinue semaglutide in patients at least 2 months before they plan to become pregnant to account for the long half-life of semaglutide.

Pediatric Use:
The safety and effectiveness of semaglutide as an adjunct to a reduced calorie diet and increased physical activity for weight reduction and long-term maintenance have been established in pediatric patients aged 12 years and older with obesity. Use of semaglutide for this indication is supported by a 68-week, double-blind, placebo-controlled clinical trial in 201 pediatric patients aged 12 years and older with a BMI corresponding to 95th percentile for age and sex and from studies in adult patients with obesity.
Adverse reactions with semaglutide treatment in pediatric patients aged 12 years and older were generally similar to those reported in adults. Pediatric patients aged 12 years and older treated with semaglutide had greater incidences of cholelithiasis, cholecystitis, hypotension, rash, and urticaria compared to adults treated with semaglutide.
There are insufficient data in pediatric patients with type 2 diabetes treated with semaglutide for obesity to determine if there is an increased risk of hypoglycemia with semaglutide treatment similar to that reported in adults. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia. In pediatric patients aged 12 years and older with type 2 diabetes, monitor blood glucose prior to starting semaglutide and during semaglutide treatment. When initiating semaglutide in pediatric patients aged 12 years and older with type 2 diabetes, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylurea) or insulin to reduce the risk of hypoglycemia.
The safety and effectiveness of semaglutide have not been established in pediatric patients less than 12 years of age.

Geriatric Use:
In the semaglutide clinical trials for weight reduction and long-term maintenance, 233 (9%) semaglutide-treated patients were aged 65



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