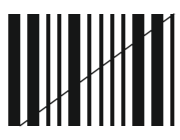


Size: 750 x 340 mm



MFL0056-00

Semaglutide Injection

2 mg/3 mL (0.68 mg/mL), 4 mg/3 mL (1.34 mg/mL) & 8 mg/3 mL (2.68 mg/mL) Prefilled Pen

Tyvenza

0.25 mg
0.5 mg
1 mg



MFL0056-00

Semaglutide Injection

2 mg/3 mL (0.68 mg/mL), 4 mg/3 mL (1.34 mg/mL) & 8 mg/3 mL (2.68 mg/mL) Prefilled Pen

Tyvenza

0.25 mg
0.5 mg
1 mg

"For the use of only a Endocrinologist or Internal Medicine Specialist only"

For Use In India

WARNING: 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.

1. GENERIC NAME Semaglutide Injection 2mg/3mL (0.68mg/mL) Prefilled Pen Semaglutide Injection 4mg/3mL (1.34mg/mL) Prefilled Pen Semaglutide Injection 8mg/3mL (2.68mg/mL) Prefilled Pen

4.1. Indication Semaglutide is indicated for the treatment of adults with insufficiently controlled type 2 diabetes as an adjunct to diet and exercise.

4.2. Pharmacology and Method of Administration Semaglutide is a GLP-1 receptor agonist. This includes post-marketing reports of increasing pancreatitis and reports with a fatal outcome.

4.3. Contraindications Semaglutide is contraindicated in patients with: A personal or family history of MTC or in patients with MEN 2.

4.4. Special Warnings and Precautions for Use Traceability In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

4.5. Drug Interactions Semaglutide delays gastric emptying and has the potential to impact the rate of absorption of concomitantly administered oral medicinal products.

4.6. Use in Special Populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.) Women of childbearing potential are recommended to use contraception when treated with semaglutide.

4.7. 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.

4.8. Undesirable Effects Clinical Safety Safety conclusion: (A) Multicenter, Randomized, Comparative, Active-Controlled, Open-Label, Phase 3 Study to Evaluate the Efficacy and Safety of Semaglutide Injection of MSN Laboratories Private Limited in Combination with Placebo (Semaglutide) Injection of Novo Nordisk in patients with Type 2 Diabetes Mellitus.

4.9. Summary of Adverse Events

Summary statistics of Adverse Event:

Table with 4 columns: Adverse Events, Semaglutide Injection (N=148), Ozempic® (N=148), Total (N=296)

Summary statistics of AE / SAE according to preferred terms and system organ class with each arm.

Table with 5 columns: System Organ Class, Preferred Term, Semaglutide Injection (n=148), Ozempic® (n=148), Total (n=296)

BE Study Safety conclusion: All per BE study (study file: An open label, balanced, randomized, two treatments, single period, single dose, parallel, bioequivalence study of Semaglutide injection 2 mg/3 mL (0.68 mg/mL) of MSN Laboratories Private Limited, India comparing with PROZem® (Semaglutide) injection 2 mg/3 mL (0.68 mg/mL) of Novo Nordisk Canada, Canada in healthy adult human subjects under fasting condition.)

BE Study Safety conclusion: All the subjects were assessed for their well-being throughout the conduct of the study. A total of 38 non-serious adverse events (Upper Respiratory Tract Infection (URI), Vomiting, Headache, Gastritis, Diarrhea and Hypoglycemia) were reported by 28 subjects, of which 13 adverse events were reported following administration of the last product, and 25 adverse events were reported with reference standard product.

Table 1: List of Adverse event(s) Drug product - Test Product (T)

Table with 4 columns: Subject, Preferred Terminology (PT), Severity, Relationship to the drug product

Adverse events reported in the study were assessed to be either mild or moderate in severity and were evaluated to be probable, possible or unlikely in relation to the study drug administered.

Table with 4 columns: Subject, Preferred Terminology (PT), Severity, Relationship to the drug product

The percentage incidence of adverse events with test product is 32.50%, and with reference standard product is 62.50%. There were no serious adverse events either observed or reported during the conduct of the study.

Reporting of suspected adverse reactions After authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9. Overdose Overdoses of up to 4 mg in a single dose, and up to 4 mg in a week have been reported in clinical trials.

5. PHARMACOLOGICAL PROPERTIES 5.1 Pharmacodynamic Properties Efficacy Analysis: Changes in HbA1c from baseline to 24 weeks (visit 7) of treatment (PP Set)

Table with 5 columns: Visit, Semaglutide Injection (T) (N=146), Ozempic® (T) (N=145), Estimated Treatment Difference vs Ozempic (95%CI) (%)

Secondary Endpoints: Changes in HbA1c from baseline to 12 weeks (visit 5) of treatment (PP Set)

Table with 5 columns: Visit, Semaglutide Injection (T) (N=146), Ozempic® (T) (N=145), Estimated Treatment Difference vs Ozempic (95%CI) (%)

Secondary efficacy end point: Change in body weight and BMI compared from baseline to 12 weeks, 24 weeks of treatment (PP Set, IN-291)

Table with 6 columns: Metabolic Parameter, Visit, Level, Semaglutide Injection (N=146), Ozempic® (N=145), Estimated Treatment Difference vs Ozempic (95%CI) (%)

Mechanism of action 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, the target for native GLP-1.

5.2 Pharmacokinetic Properties Absorption Absolute bioavailability of semaglutide is 89%. Maximum concentration of semaglutide is reached 1 to 3 days post dose.

5.3 Safety Semaglutide has not been studied in pediatric patients.

7.1 Contraindications None

7.2 Packing Information One mono carton contains 1 pen with prefilled cartridge along with needles.

7.3 Shelf life 24 Months

7.4 Storage and Handling Instructions Long-term Storage (Unopened Pen) Store in a refrigerator between 2°C to 8°C. Do not freeze.

7.5 Patient Information None

8. PATIENT COUNSELLING INFORMATION Risk of Thyroid C-cell Tumors Inform patients that semaglutide causes thyroid C-cell tumors in rodents and that the human relevance of this finding has not been determined.

Pancreatitis Inform patients of the potential risk for pancreatitis. Instruct patients to discontinue semaglutide promptly and contact their physician if pancreatitis is suspected.

Diabetic Retinopathy Complications Inform patients that their physician if changes in vision are experienced during treatment with semaglutide.

Never Share an semaglutide Pen Between Patients Advise patients that they must never share an semaglutide pen with another person, even if the needle is changed, because doing so carries a risk for transmission of blood-borne pathogens.

Hypoglycaemia with Concomitant Use of Insulin Secretagogues or Insulin Inform patients that the risk of hypoglycaemia is increased when semaglutide is used with an insulin secretagogue (such as a sulfonylurea) or insulin. Educate patients on the signs and symptoms of hypoglycaemia.

Acute Kidney Injury Advise patients treated with semaglutide of the potential risk of dehydration due to gastrointestinal adverse reactions and take precautions to avoid fluid depletion. Inform patients of the potential risk for worsening renal function and explain the associated signs and symptoms of renal impairment, as well as the possibility of dialysis as a medical intervention if acute kidney injury occurs.

Hypersensitivity Reactions Inform patients that serious hypersensitivity reactions have been reported during postmarketing use of semaglutide. Advise patients on the symptoms of hypersensitivity reactions and instruct them to stop taking semaglutide and seek medical advice promptly if such symptoms occur.

Acute Gallbladder Disease Inform patients of the potential risk for cholelithiasis or cholecystitis. Instruct patients to contact their physician if cholelithiasis or cholecystitis is suspected for appropriate clinical follow-up.

Pregnancy Advise a pregnant woman of the potential risk to a fetus. Advise women to inform their healthcare provider if they are pregnant or intend to become pregnant.

Missed doses Inform patients if a dose is missed, it should be administered as soon as possible 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.

9. DETAILS OF MANUFACTURER MSN Laboratories Pvt. Ltd. At: OneSource Specialty Pharma Limited, Plot No. 2-D1, Obedanshalli, Doddaballura, 3rd Phase, Industrial Area, Doddaballura Taluk, Bengaluru - 561203, India

10. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE KTC28A0925/2024

11. DATE OF REVISION Jan 2026

INSTRUCTIONS FOR USE Semaglutide (sem-a-gloo-tide) Injection, for subcutaneous use

0.25 mg or 0.5 mg doses (pen delivers doses in 0.25 mg or 0.5 mg increments only)

Instructions for use diagrams: A. Read these instructions carefully before using your semaglutide injection pen. B. Do not use your pen without proper training from your healthcare provider. C. Do not share your semaglutide injection pen with other people.

Instructions for use diagrams: D. Push the needle straight onto the pen. Turn until it is on tight. E. The needle is covered by 2 caps. You must remove both caps, if you forget to remove both caps, you will not inject any medicine.

Instructions for use diagrams: F. Pull off the inner needle cap and throw it away. A drop of semaglutide injection may appear at the needle tip. This is normal, but you must still check the semaglutide injection flow if you use a new pen for the first time.

Instructions for use diagrams: G. Always use a new needle for each injection. This will reduce the risk of contamination, infection, leakage of semaglutide injection, and blood needles leading to the wrong dose.

Instructions for use diagrams: H. Hold the pen with the needle pointing up. Press and hold in the dose button until the dose counter shows 0. The 0 must line up with the dose pointer.

Instructions for use diagrams: I. A drop of semaglutide injection will appear at the needle tip. If no drop appears, repeat Step 2 above as shown in Figure G and Figure H up to 6 times. If there is still no drop, change the needle and repeat Step 2 as shown in Figure G and Figure H 1 more time.

Instructions for use diagrams: J. Always make sure that a drop appears at the needle tip before you use a new pen for the first time. This makes sure that no semaglutide injection flows.

Instructions for use diagrams: K. If no drop appears, you will not inject any semaglutide injection, even though the dose counter may move. This may mean that there is a blocked or damaged needle.

Instructions for use diagrams: L. Always use the dose counter and the dose pointer to see how many mg you select. You will hear a "click" every time you turn the dose selector.

Instructions for use diagrams: M. How much semaglutide injection is left? To see how much semaglutide injection is left in your pen, use the dose counter.

Instructions for use diagrams: N. Insert the needle into your skin as your healthcare provider has shown you. Insert the pen so you can see the dose counter. Do not cover it with your fingers. This could stop the injection.

Instructions for use diagrams: O. 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.

750 mm

340 mm Front

Count 6 seconds while keeping the dose button pressed.
If the needle is removed earlier, you may see a stream of semaglutide injection 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.

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 injection even though the dose counter 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 injection 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 semaglutide injection 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 injection 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 injection, and blocked needles leading to the wrong dose. If the needle is blocked, you will not inject any semaglutide injection.
Always dispose of the needle after each injection.

Disposing of used semaglutide injection pens and needles:

- Put your used semaglutide injection pen and needle in a sharps disposal container right away after use.
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a light-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant
 - 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 injection 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 injection 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 injection 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 injection pen?

- Store your new, unused semaglutide injection 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 injection pen you are using should be disposed of (thrown away) after 56 days, even if it still has semaglutide injection left in it. Write the disposal date on your calendar.
- Do not freeze semaglutide injection. Do not use semaglutide injection if it has been frozen.
- Unused semaglutide injection 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 injection pens directly next to the cooling element.
- Keep semaglutide injection away from heat and out of the light.
- Keep the pen cap on when not in use.
- Keep semaglutide injection and all medicines out of the reach of children.

INSTRUCTIONS FOR USE Semaglutide(sem-a-gluo-tide) Injection, for subcutaneous use 2 mg doses
(pen delivers doses in 2 mg increments only)

Read these instructions carefully before using your semaglutide injection pen.

- Do not use your pen without proper training from your healthcare provider. Make sure that you know how to give yourself an injection with the pen before you start your treatment.
- Do not share your semaglutide injection pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

⚠️ If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use the semaglutide injection pen.

Start by checking your pen to make sure that it contains semaglutide injection, then look at the pictures below to get to know the different parts of your pen and needle.

- Your pen is a pre-filled, single-patient-use, dial-a-dose pen. It contains 2 mg of semaglutide, and you can select doses of 2 mg. Each pre-filled pen contains 4 doses of 2 mg.
- Your pen is made to be used with BD Ultra-Fine™ disposable needles up to a length of 8 mm.
- BD Ultra-Fine™ 32G 4 mm disposable needles are included with your semaglutide injection pen.
- Always use a new needle for each injection.

Supplies you will need to give your semaglutide injection:

- Semaglutide injection 2 mg pen
- a new BD Ultra-Fine™ needle
- 1 alcohol swab
- 1 gauze pad or cotton ball
- 1 sharps disposal container for throwing away

Step 1: Prepare your pen with a new needle

- Wash your hands with soap and water.
- Check the name and colored label of your pen, to make sure that it contains semaglutide injection. This is especially important if you take more than 1 type of medicine.
- Pull off the pen cap.
- Check that the semaglutide injection medicine in your pen is clear and colorless. Look through the pen window. If semaglutide injection looks cloudy or contains particles, do not use the pen.
- Take a new needle, and tear off the paper tab. Do not attach a new needle to your pen until you are ready to give your injection.
- Push the needle straight onto the pen. Turn until it is on tight.

The needle is covered by 2 caps. You must remove both caps. If you forget to remove both caps, you will not inject any medicine. Pull off the outer needle cap. Do not throw it away.

Pull off the inner needle cap and throw it away. A drop of semaglutide injection may appear at the needle tip. This is normal, but you must still check the semaglutide injection flow if you use a new pen for the first time.

Always use a new needle for each injection. This will reduce the risk of contamination, infection, leakage of semaglutide injection, and blocked needles leading to the wrong dose. Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious infection from them. Never use a bent or damaged needle.

Step 2: First Time Use for Each New Pen: Check the semaglutide injection flow

- Check the semaglutide injection flow before the first injection with each new pen only. If your semaglutide injection pen is already in use, go to Step 3 "Select your dose".
- Turn the dose selector until the dose counter shows the flow check symbol (—).

Hold the pen with the needle pointing up. Press and hold in the dose button until the dose counter shows 0. The 0 must line up with the dose pointer.

A drop of semaglutide injection will appear at the needle tip.
If no drop appears, repeat Step 2 above as shown in Figure G and Figure H up to 6 times. If there is still no drop, change the needle and repeat Step 2 as shown in Figure G and Figure H 1 more time.

Do not use the pen if a drop of semaglutide injection still does not appear.

Always make sure that a drop appears at the needle tip before you use a new pen for the first time. This makes sure that semaglutide injection flows.

If no drop appears, you will not inject any semaglutide injection, even though the dose counter may move. This may mean that there is a blocked or damaged needle.

A small drop may remain at the needle tip, but it will not be injected. Only check the semaglutide injection flow before your first injection with each new pen.

Step 3: Select your dose

- Turn the dose selector until the dose counter stops and shows your 2 mg dose.

The dashed line in the dose counter will (I) guide you to 2 mg dose.

Always use the dose counter and the dose pointer to see that 2 mg has been selected. 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 doses of 2 mg can be selected with the dose selector. The 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 2 mg has been selected.

You can only select 2 mg for each dose. When your pen contains less than 2 mg, the dose counter stops before 2 mg is shown.

The dose selector clicks differently when turned forward or backward. Do not count the pen clicks.

How much semaglutide injection is left?

- To see how much semaglutide injection is left in your pen, use the dose counter.

Turn the dose selector until the dose counter stops.

- If it shows 2, at least 2 mg is left in your pen. If the dose counter stops before 2 mg, there is not enough semaglutide injection left for a full dose of 2 mg.

If there is not enough semaglutide injection left in your pen for a full dose, do not use it. Use a new semaglutide injection 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 (See Figure K).
- 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 injection 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.

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 injection even though the dose counter 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 injection 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 semaglutide injection 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 injection 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 injection, and blocked needles leading to the wrong dose. If the needle is blocked, you will not inject any semaglutide injection.
Always dispose of the needle after each injection.

Disposing of used semaglutide injection pens and needles:

- Put your used semaglutide injection pen and needle in a sharps disposal container right away after use.
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a light-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant
 - 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 injection 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 injection 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 injection 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 injection pen?

- Store your new, unused semaglutide injection 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 injection pen you are using should be disposed of (thrown away) after 56 days, even if it still has semaglutide injection left in it. Write the disposal date on your calendar.
- Do not freeze semaglutide injection. Do not use semaglutide injection if it has been frozen.
- Unused semaglutide injection 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 injection pens directly next to the cooling element.
- Keep semaglutide injection away from heat and out of the light.
- Keep the pen cap on when not in use.
- Keep semaglutide injection and all medicines out of the reach of children.

INSTRUCTIONS FOR USE Semaglutide(sem-a-gluo-tide) Injection, for subcutaneous use 1 mg doses
(pen delivers doses in 1 mg increments only)

Read these instructions carefully before using your semaglutide injection pen.

- Do not use your pen without proper training from your healthcare provider. Make sure that you know how to give yourself an injection with the pen before you start your treatment.
- Do not share your semaglutide injection pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

⚠️ If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use the semaglutide injection pen.

Start by checking your pen to make sure that it contains semaglutide injection, then look at the pictures below to get to know the different parts of your pen and needle.

- Your pen is a pre-filled, single-patient-use, dial-a-dose pen. It contains 4 mg of semaglutide, and you can select doses of 1 mg.
- Your pen is made to be used with BD Ultra-Fine™ disposable needles up to a length of 8 mm.
- BD Ultra-Fine™ 32G 4 mm disposable needles are included with your semaglutide injection pen.
- Always use a new needle for each injection.

Supplies you will need to give your semaglutide injection:

- Semaglutide injection 1 mg pen
- a new BD Ultra-Fine™ needle
- 1 alcohol swab
- 1 gauze pad or cotton ball
- 1 sharps disposal container for throwing away

Step 1: Prepare your pen with a new needle

- Wash your hands with soap and water.
- Check the name and colored label of your pen, to make sure that it contains semaglutide injection. This is especially important if you take more than 1 type of medicine.
- Pull off the pen cap.
- Check that the semaglutide injection medicine in your pen is clear and colorless. Look through the pen window. If semaglutide injection looks cloudy or contains particles, do not use the pen.
- Take a new needle, and tear off the paper tab. Do not attach a new needle to your pen until you are ready to give your injection.
- Push the needle straight onto the pen. Turn until it is on tight.

The needle is covered by 2 caps. You must remove both caps. If you forget to remove both caps, you will not inject any medicine. Pull off the outer needle cap. Do not throw it away.

Pull off the inner needle cap and throw it away. A drop of semaglutide injection may appear at the needle tip. This is normal, but you must still check the semaglutide injection flow if you use a new pen for the first time.

Always use a new needle for each injection. This will reduce the risk of contamination, infection, leakage of semaglutide injection, and blocked needles leading to the wrong dose. Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious infection from them. Never use a bent or damaged needle.

Step 2: First Time Use for Each New Pen: Check the semaglutide injection flow

- Check the semaglutide injection flow before the first injection with each new pen only. If your semaglutide injection pen is already in use, go to Step 3 "Select your dose".
- Turn the dose selector until the dose counter shows the flow check symbol (—).

Hold the pen with the needle pointing up. Press and hold in the dose button until the dose counter shows 0. The 0 must line up with the dose pointer.

A drop of semaglutide injection will appear at the needle tip.
If no drop appears, repeat Step 2 above as shown in Figure G and Figure H up to 6 times. If there is still no drop, change the needle and repeat Step 2 as shown in Figure G and Figure H 1 more time.

Do not use the pen if a drop of semaglutide injection still does not appear.

Always make sure that a drop appears at the needle tip before you use a new pen for the first time. This makes sure that semaglutide injection flows.

If no drop appears, you will not inject any semaglutide injection, even though the dose counter may move. This may mean that there is a blocked or damaged needle.

A small drop may remain at the needle tip, but it will not be injected. Only check the semaglutide injection flow before your first injection with each new pen.

Push the needle straight onto the pen. Turn until it is on tight.

The needle is covered by 2 caps. You must remove both caps. If you forget to remove both caps, you will not inject any medicine. Pull off the outer needle cap. Do not throw it away.

Pull off the inner needle cap and throw it away. A drop of semaglutide injection may appear at the needle tip. This is normal, but you must still check the semaglutide injection flow if you use a new pen for the first time.

Always use a new needle for each injection. This will reduce the risk of contamination, infection, leakage of semaglutide injection, and blocked needles leading to the wrong dose. Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious infection from them. Never use a bent or damaged needle.

Step 2: First Time Use for Each New Pen: Check the semaglutide injection flow

- Check the semaglutide injection flow before the first injection with each new pen only. If your semaglutide injection pen is already in use, go to Step 3 "Select your dose".
- Turn the dose selector until the dose counter shows the flow check symbol (—).

Hold the pen with the needle pointing up. Press and hold in the dose button until the dose counter shows 0. The 0 must line up with the dose pointer.

A drop of semaglutide injection will appear at the needle tip.
If no drop appears, repeat Step 2 above as shown in Figure G and Figure H up to 6 times. If there is still no drop, change the needle and repeat Step 2 as shown in Figure G and Figure H 1 more time.

Do not use the pen if a drop of semaglutide injection still does not appear.

Always make sure that a drop appears at the needle tip before you use a new pen for the first time. This makes sure that semaglutide injection flows.

If no drop appears, you will not inject any semaglutide injection, even though the dose counter may move. This may mean that there is a blocked or damaged needle.

A small drop may remain at the needle tip, but it will not be injected. Only check the semaglutide injection flow before your first injection with each new pen.

Step 3: Select your dose

- Turn the dose selector until the dose counter stops and shows your 1 mg dose.

The dashed line in the dose counter will (I) guide you to 1 mg.

Always use the dose counter and the dose pointer to see how many mg you select. 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 doses of 1 mg can be selected with the dose selector. 1 mg 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 how many mg you select for each dose.

You can only select 1 mg for each dose. When your pen contains less than 1 mg, the dose counter stops before 1 mg is shown.

The dose selector clicks differently when turned forward or backward. Do not count the pen clicks.

How much semaglutide injection is left?

- To see how much semaglutide injection 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 injection left for a full dose of 1 mg.

If there is not enough semaglutide injection left in your pen for a full dose, do not use it. Use a new semaglutide injection 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 (See Figure K).
- 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 injection 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.

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 injection even though the dose counter 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 injection 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 semaglutide injection 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 injection 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 injection, and blocked needles leading to the wrong dose. If the needle is blocked, you will not inject any semaglutide injection.
Always dispose of the needle after each injection.

Disposing of used semaglutide injection pens and needles:

- Put your used semaglutide injection pen and needle in a sharps disposal container right away after use.
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a light-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant
 - 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 injection 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 injection 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 injection 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 injection pen?

- Store your new, unused semaglutide injection 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 injection pen you are using should be disposed of (thrown away) after 56 days, even if it still has semaglutide injection left in it. Write the disposal date on your calendar.
- Do not freeze semaglutide injection. Do not use semaglutide injection if it has been frozen.
- Unused semaglutide injection 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 injection pens directly next to the cooling element.
- Keep semaglutide injection away from heat and out of the light.
- Keep the pen cap on when not in use.
- Keep semaglutide injection and all medicines out of the reach of children.

Marketed by:
CORONA Remedies Limited
Village: Jatoli, Post Office - Gachghat,
Tehsil Solan, Distt. Solan (H.P.)-173 223.

Manufactured in India By:
MSN Lifesciences Pvt. Ltd.
All OneSource Specialty Pharma Limited,
Plot No. 2-D1, Chaudhahalli, Doodaballapura,
3rd Phase, Industrial Area, Doodaballapura Taluk,
Bangalore Rural - 561203, India.