340 mm

170 mm | 170 mm

55 mm

750 mm

MFLL0059-00 4470 1200014470

SEMALIX™

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

MFLL0059-00 4470 1200014470

SEMALIX™

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

For Use in India

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

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.**
- **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 (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.**

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Semaglutide Injection 2mg/3mL (0.68mg/mL)
Each 1 ml of Semaglutide injection contains.........0.68mg of Semaglutide
Semaglutide Injection 4mg/3mL (1.34mg/mL)
Each 1 ml of Semaglutide injection contains.........1.34mg of Semaglutide
Semaglutide Injection 8mg/3mL (2.68mg/mL)
Each 1 ml of Semaglutide injection contains.........2.68mg of Semaglutide

3. DOSAGE FORM AND STRENGTH

Injection (Prefilled Pen); 2mg/3mL (0.68mg/mL), 4mg/3mL (1.34mg/mL) and 8mg/3mL (2.68mg/mL)

4. CLINICAL PARTICULARS

4.1. Indication

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

- as monotherapy, when metformin-based therapy is considered inappropriate due to intolerance or contraindications.
- in addition to the other medicinal products for the treatment of diabetes

4.2. Posology and Method of Administration

Posology

The starting dose is 0.25 mg semaglutide once weekly. After 4 weeks the dose should be increased to 0.5 mg once weekly. After at least 4 weeks with a dose of 0.5 mg once weekly, the dose can be increased to 1 mg once weekly to further improve glycaemic control. After at least 4 weeks with a dose of 1 mg once weekly, the dose can be increased to 2 mg once weekly to further improve glycaemic control.
Semaglutide 0.25 mg is not a maintenance dose. Weekly doses higher than 2 mg are not recommended.
When Semaglutide is added to existing metformin can be continued unchanged.

Missed dose

If a dose is missed, it should be administered as soon as possible and 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. In each case, patients can then resume their regular once weekly dosing schedule.

Changing the dosing day

The day of weekly administration can be changed if necessary, as long as the time between two doses is at least 3 days (>72 hours). After selecting a new dosing day, once-weekly dosing should be continued.

Special populations

Elderly

No dose adjustment is required based on age.

Renal impairment

No dose adjustment is required for patients with mild, moderate or severe renal impairment.
Experience with the use of Semaglutide in patients with severe renal impairment is limited.

Hepatic impairment

No dose adjustment is required for patients with hepatic impairment. Experience with the use of Semaglutide in patients with severe hepatic impairment is limited. Caution should be exercised when treating these patients with Semaglutide.

Paediatric population

The safety and efficacy of Semaglutide in children and adolescents below 18 years have not yet been established. No data are available.

Method of administration

Subcutaneous use.
Semaglutide is to be injected subcutaneously in the abdomen, in the thigh or in the upper arm. The injection site can be changed without dose adjustment. Semaglutide should not be administered intravenously or intramuscularly.
Semaglutide is to be administered once weekly at any time of the day, with or without meals.

4.3. Contraindications

Semaglutide is contraindicated in patients with:

- A personal or family history of MTC or in patients with MEN 2.
- A serious hypersensitivity reaction to semaglutide or to any of the excipients in Semaglutide.

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.

General

Semaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Semaglutide is not a substitute for insulin. Diabetic ketoacidosis has been reported in insulin-dependent patients whom had rapid discontinuation or dose reduction of insulin when treatment with a GLP-1 receptor agonist is started.
There is no experience in patients with congestive heart failure NYHA class IV and Semaglutide is therefore not recommended in these patients.

Aspiration in association with general anaesthesia or deep sedation

Cases of pulmonary aspiration have been reported in patients receiving GLP-1 receptor agonists undergoing general anaesthesia or deep sedation. Therefore, the increased risk of residual gastric content due to delayed gastric emptying should be considered prior to performing procedures with general anaesthesia or deep sedation.

Gastrointestinal effects

Use of GLP-1 receptor agonists may be associated with gastrointestinal adverse reactions. This should be considered when treating patients, with impaired renal function as nausea, vomiting, and diarrhoea may cause dehydration which could cause a deterioration of renal function.

Acute pancreatitis

Semaglutide has not been studied in patients with a history of pancreatitis, and should be used with caution in these patients.
Acute pancreatitis has been reported in patients treated with GLP-1 receptor agonists. This includes post-marketing reports of necrotising pancreatitis and reports with a fatal outcome. Patients should be informed of the symptoms of acute pancreatitis, including persistent, severe abdominal pain. Patients should be advised to seek immediate medical attention if they occur.
If pancreatitis is suspected, Semaglutide should be discontinued. If the diagnosis of pancreatitis is confirmed, Semaglutide should not be restarted.
In the absence of other signs and symptoms of acute pancreatitis, elevations in pancreatic enzymes alone are not predictive of acute pancreatitis.

Hypoglycaemia

Patients treated with Semaglutide in combination with a sulfonylurea or insulin may have an increased risk of hypoglycaemia.
The risk of hypoglycaemia can be lowered by reducing the dose of sulfonylurea or insulin when initiating treatment with Semaglutide.

Non-arteritic anterior ischaemic optic neuropathy (NAION)

Data from epidemiological studies may indicate an increased risk of non-arteritic anterior ischaemic optic neuropathy (NAION) during treatment with Semaglutide. There is no identified time interval for when NAION may develop following treatment start. Patients reporting a sudden loss of vision (including partial loss) should be urgently referred for ophthalmological examination and treatment with Semaglutide should be discontinued if NAION is confirmed.

Diabetic retinopathy

In patients with diabetic retinopathy treated with insulin and Semaglutide, an increased risk of developing diabetic retinopathy complications has been observed (see section 4.8). Caution should be exercised when using Semaglutide in patients with diabetic retinopathy treated with insulin.These patients should be monitored closely and treated according to clinical guidelines.
Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy, but other mechanisms cannot be excluded.
There is no experience with Semaglutide 2 mg in patients with type 2 diabetes with uncontrolled or potentially unstable diabetic retinopathy and Semaglutide 2 mg is therefore not recommended in these patients.

Sodium content

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

4.5. Drug Interactions

Semaglutide delays gastric emptying and has the potential to impact the rate of absorption of concomitantly administered oral medicinal products. Semaglutide should be used with caution in patients receiving oral medicinal products that require rapid gastrointestinal absorption.

Paracetamol

Semaglutide delays the rate of gastric emptying as assessed by paracetamol pharmacokinetics during a standardised meal test. Paracetamol AUC0-60min and Cmax were decreased by 27% and 23%, respectively, following concomitant use of Semaglutide 1 mg. The total paracetamol exposure (AUC0-5h) was not affected. No clinically relevant effect on the rate of gastric emptying was observed with Semaglutide 2.4 mg, following 20 weeks of administration of Semaglutide, probably due to a tolerance effect. No dose adjustment of paracetamol is necessary when administered with Semaglutide.

Oral contraceptives

Semaglutide is not anticipated to decrease the effect of oral contraceptives as Semaglutide did not change the overall exposure of ethinylestradiol and levonorgestrel to a clinically relevant degree when an oral contraceptive combination medicinal product (0.03 mg ethinylestradiol/0.15 mg levonorgestrel) was co-administered with Semaglutide. Exposure of ethinylestradiol was not affected; an increase of 20% was observed for levonorgestrel exposure at steady state. Cmax was not affected for any of the compounds.

Atorvastatin

Semaglutide did not change the overall exposure of atorvastatin following a single dose administration of atorvastatin (40 mg). Atorvastatin Cmax was decreased by 38%. This was assessed not to be clinically relevant.

Digoxin

Semaglutide did not change the overall exposure or Cmax of digoxin following a single dose of digoxin (0.5 mg).

Metformin

Semaglutide did not change the overall exposure or Cmax of metformin following dosing of 500 mg twice daily over 3.5 days.

Warfarin and other coumarin derivatives

Semaglutide did not change the overall exposure or Cmax of R- and S-warfarin following a single dose of warfarin (25 mg), and the pharmacodynamic effects of warfarin as measured by the international normalised ratio (INR) were not affected in a clinically relevant manner. However, cases of decreased INR have been reported during concomitant use of acenocoumarol and semaglutide. Upon initiation of semaglutide treatment in patients on warfarin or other coumarin derivatives, frequent monitoring of INR is recommended.

4.6. Use in Special Populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Women of childbearing potential

Women of childbearing potential are recommended to use contraception when treated with semaglutide.

Pregnancy

Studies in animals have shown reproductive toxicity. There are limited data from the use of semaglutide in pregnant women. Therefore, semaglutide should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, semaglutide should be discontinued. Semaglutide should be discontinued at least 2 months before a planned pregnancy due to the long half-life.

Breast-feeding

In lactating rats, semaglutide was excreted in milk. As a risk to a breast-fed child cannot be excluded, semaglutide should not be used during breast-feeding.

Fertility

The effect of semaglutide on fertility in humans is unknown. Semaglutide did not affect male fertility in rats. In female rats, an increase in oestrous length and a small reduction in number of ovulations were observed at doses associated with maternal body weight loss.

Pediatric Use

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

Geriatric Use

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

Hepatic Impairment

No dose adjustment of semaglutide is recommended for patients with hepatic impairment. In a study in subjects with different degrees of hepatic impairment, no clinically relevant change in semaglutide pharmacokinetics (PK) was observed.

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 Study 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 Comparison with Ozempic (Semaglutide) Injection of Novo Nordisk in patients with Type 2 Diabetes Mellitus)
The safety evaluation of Semaglutide Injection (Test) in this randomized, comparative clinical study demonstrates that the investigational product is safe and well tolerated, with a safety profile that is comparable to the reference product Ozempic® and consistent with the established pharmacological class of GLP-1 receptor agonists.

Across the safety population, the overall incidence, nature, and severity of adverse events were similar between the Test and Reference treatment arms. The majority of reported adverse events were mild to moderate in intensity, transient, and resolved either spontaneously or with standard symptomatic management. No clinically meaningful imbalances in treatmentemergent adverse events were observed between groups, indicating comparable tolerability.

Gastrointestinal adverse events constituted the most frequently reported events in both treatment arms, including nausea, vomiting, gastritis, diarrhoea, constipation, and abdominal distension. These events occurred at comparable frequencies between the Test and Reference groups and were consistent with the known and expected safety profile of semaglutide. Importantly, no severe (Grade ≥3) gastrointestinal events were reported, and none resulted in treatment discontinuation.

The incidence of hypoglycaemia was low in both treatment arms, with all reported events being mild in severity. No severe or clinically significant hypoglycaemic episodes occurred, and no participant discontinued treatment due to hypoglycaemia, confirming that effective glycaemic control was achieved without an increased risk of hypoglycaemic events.

Serious adverse events were rare, with no deaths reported during the study. There were no clinically relevant differences between treatment arms with respect to serious adverse events, and none were considered related to the investigational product. Furthermore, no participant discontinued the study due to an adverse event, underscoring the overall good tolerability of Semaglutide Injection.

Evaluation of adverse events by causality showed that gastrointestinal events were more frequently assessed as related to study medication, which is consistent with the known mechanism of action of GLP-1 receptor agonists. Non-gastrointestinal adverse events were predominantly assessed as unrelated to study treatment. No new or unexpected adverse drug reactions were identified.

Clinical laboratory parameters, vital signs, physical examination findings, and injection site assessments did not reveal any clinically meaningful abnormalities or concerning trends attributable to Semaglutide Injection. No safety concerns related to immunogenicity or diabetic retinopathy progression were identified during the study period.

Overall, the comprehensive safety data demonstrate that Semaglutide Injection has a favourable and well-characterized safety profile, comparable to that of the reference product Ozempic®. The absence of new safety signals, low incidence of serious and severe adverse events, and high treatment tolerability support the conclusion that Semaglutide Injection is safe for clinical use in patients with type 2 diabetes mellitus and has a positive benefit–risk balance.

Descriptive statistics of Adverse Event:

Adverse Events	Semaglutide Injection (T) (N=148)	Ozempic® (T) (N=148)	Total (N=296)
Number of Subjects	68 (45.95%)	74 (50.00%)	138 (47.97%)
Number of Events	149	152	301

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

System Organ Class	Preferred Term	Semaglutide Injection (T) (n=148) [e]	Ozempic® (R) (n=148) [e]	Total (n=296) [e]
Gastrointestinal disorders	Abdominal distension	9 (6.1%) [16]	4 (2.7%) [8]	13 (4.4%) [24]
	Abdominal pain upper	1 (0.7%) [1]	0 (0.0%) [0]	1 (0.3%) [1]
	Constipation	5 (3.4%) [5]	7 (4.7%) [9]	12 (4.1%) [14]
	Diarrhoea	7 (4.7%) [8]	11 (7.4%) [13]	18 (6.1%) [21]
	Dyspepsia	6 (4.1%) [8]	3 (2.0%) [6]	9 (3.0%) [14]
	Eructation	3 (2.0%) [3]	0 (0.0%) [0]	3 (1.0%) [3]
	Gastritis	16 (10.8%) [22]	15 (10.1%) [18]	31 (10.5%) [40]
	Hyperchlorhydria	2 (1.4%) [2]	3 (2.0%) [4]	5 (1.7%) [6]
	Nausea	31 (20.9%) [43]	28 (18.9%) [39]	59 (19.9%) [82]
General disorders and administration site conditions	Vomiting	17 (11.5%) [22]	23 (15.5%) [34]	40 (13.5%) [56]
	Asthenia	1 (0.7%) [1]	0 (0.0%) [0]	1 (0.3%) [1]
	Decreased appetite	1 (0.7%) [1]	3 (2.0%) [3]	4 (1.4%) [4]
	Fatigue	0 (0.0%) [0]	2 (1.4%) [2]	2 (0.7%) [2]
	Injection site swelling	0 (0.0%) [0]	1 (0.7%) [1]	1 (0.3%) [1]
	Pain	2 (1.4%) [2]	0 (0.0%) [0]	2 (0.7%) [2]
	Pyrexia	5 (3.4%) [5]	4 (2.7%) [4]	9 (3.0%) [9]
Infections and infestations	Nasopharyngitis	1 (0.7%) [1]	1 (0.7%) [1]	2 (0.7%) [2]
	Rhinitis	0 (0.0%) [0]	1 (0.7%) [1]	1 (0.3%) [1]
Metabolism and nutrition disorders	Hypoglycaemia	1 (0.7%) [1]	2 (1.4%) [2]	3 (1.0%) [3]
Nervous system disorders	Dizziness	2 (1.4%) [2]	1 (0.7%) [1]	3 (1.0%) [3]
	Headache	2 (1.4%) [3]	4 (2.7%) [4]	6 (2.0%) [7]
Respiratory, thoracic and mediastinal disorders	Cough	1 (0.7%) [1]	1 (0.7%) [1]	2 (0.7%) [2]
	RHINORRHEA	1 (0.7%) [1]	0 (0.0%) [0]	1 (0.3%) [1]
Vascular disorders	Dizziness	1 (0.7%) [1]	1 (0.7%) [1]	2 (0.7%) [2]
n-number of subjects e-number of events				

BE Study Safety conclusion:

As per BE study (study title: An open label, balanced, randomized, two treatments, single period, single dose, parallel, bioequivalence study of Semaglutide injection 2 mg/3 mL (0.68 MSNO mg/mL) of MSN laboratories Private Limited, India comparing with PROzempic® (Semaglutide) injection 2 mg/3 mL (0.68 mg/mL) of Novo Nordisk Canada, Canada in healthy adult human subjects under fasting condition.) the following ADRs have been identified:

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 26 subjects, of which 13 adverse events were reported following administration of the test product, and 25 adverse events were reported with reference standard product.

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

Subject	Preferred Terminology (PT)	Severity	Relationship to the drug product
S09	Headache	Moderate	Unlikely
S36	Diarrhoea	Moderate	Possible
	Vomiting	Moderate	Possible
S44	Hypoglycemia	Mild	Probable
	Diarrhoea	Moderate	Possible
S49	Diarrhoea	Moderate	Possible
	Vomiting	Moderate	Possible
S59	Vomiting	Mild	Probable
S62	Vomiting	Moderate	Probable
S63	Vomiting	Moderate	Probable
S74	Vomiting	Moderate	Unlikely
	Upper Respiratory tract infection	Mild	Probable
S75	Hypoglycemia	Mild	Probable
S80	Hypoglycemia	Moderate	Probable

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. Subjects were followed up by the Investigator(s)/Physician(s), and all the adverse events reported in the study resolved without any sequelae.

Subject	Preferred Terminology (PT)	Severity	Relationship to the drug product
S08	Vomiting	Moderate	Possible
	Upper Respiratory tract infection	Moderate	Probable
S11	Headache	Moderate	Unlikely
S18	Gastritis	Moderate	Possible
	Diarrhoea	Moderate	Possible
S21	Diarrhoea	Moderate	Probable
	Vomiting	Moderate	Probable
	Gastritis	Moderate	Probable
S38	Vomiting	Moderate	Possible
	Gastritis	Moderate	Possible
S45	Nausea	Moderate	Possible
S52	Vomiting	Moderate	Probable
S58	Hypoglycemia	Mild	Probable
	Headache	Moderate	Unlikely
S60	Vomiting	Moderate	Probable
S64	Vomiting	Moderate	Probable
S66	Diarrhoea	Moderate	Probable
	Vomiting	Moderate	Probable
	Hypoglycemia	Mild	Probable
S68	Diarrhoea	Moderate	Probable
S69	Hypoglycemia	Mild	Probable
S76	Hypoglycemia	Mild	Probable
S78	Hypoglycemia	Mild	Probable
S79	Hypoglycemia	Mild	Probable
	Hypoglycemia	Moderate	Probable

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. Thus, it can be concluded that both the test and reference standard products were relatively well tolerated in the selected study population at the administered dose levels.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. To report Suspected Adverse Reactions, contact MSN Laboratories Private Limited at pharmacovigilance@msnlabs.com or through company website www.msnlabs.com->Contact us->Medical Enquiry/ to report a side effect. You can also report side effects directly via the National Pharmacovigilance Programme of India by calling on 1800 180 3024 or you can report to MSN Labs on +91- 40 38265227 (Direct line); +91 7331134745 (WhatsApp). By reporting side effects, you can help provide more information on the safety of this 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. The most commonly reported adverse reaction was nausea. All patients recovered without complications.
There is no specific antidote for overdose with semaglutide. 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.

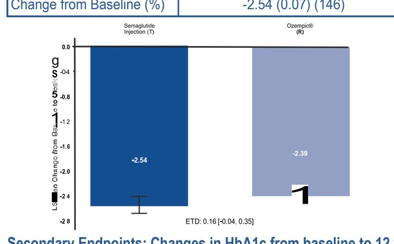
5. PHARMACOLOGICAL PROPERTIES

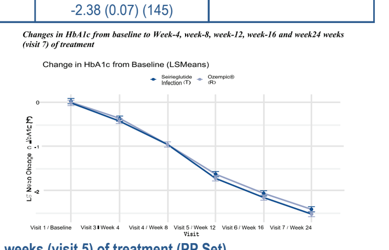
5.1 Pharmacodynamic Properties

Efficacy Analysis:

Changes in HbA1c from baseline to 24 weeks (visit 7) of treatment (PP Set)

Visit	Semaglutide Injection (T) (N=146)	Ozempic® (T) (N=145)	Estimated Treatment Difference vs Ozempic (95%CI) (%)
Baseline (%)	8.93 ± 0.75 (146)	9.05 ± 0.80 (145)	0.17 (-0.03, 0.36)
Week 24 (%)	6.43 ± 0.82 (146)	6.63 ± 0.90 (145)	
Change from Baseline (%)	-2.54 (0.07) (146)	-2.38 (0.07) (145)	

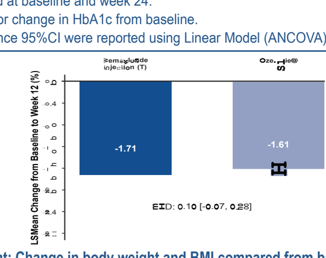




Secondary Endpoints: Changes in HbA1c from baseline to 12 weeks (visit 5) of treatment (PP Set)

Visit	Semaglutide Injection (T) (N=146)	Ozempic® (T) (N=145)	Estimated Treatment Difference vs Ozempic (95%CI) (%)	p-value
Baseline (%)	8.93 ± 0.75 (146)	9.05 ± 0.80 (145)	0.11 (-0.07, 0.29)	-
Week 12 (%)	7.24 ± 0.84 (146)	7.24 ± 0.93 (145)		0.217
Change from Baseline (%)	-1.71 (0.06) (146)	-1.60 (0.06) (145)		-

mean± SD (n) were reported at baseline and week 24.
LSM(SE)(n) were reported for change in HbA1c from baseline.
Estimated Treatment difference 95%CI were reported using Linear Model (ANCOVA).



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

Metabolic Parameter	Visit	Level	Semaglutide Injection (T) (N=146)	Ozempic® (R) (N=145)	Estimated Treatment Difference [95%CI]	p-value
Body Weight	VISIT 2 / Baseline	Mean ± SD	**71.6** ± 12.6 (146)	**73.1** ± 14.2 (145)	NA	NA
		Change from Baseline				
	VISIT 5 / WEEK 12	Mean ± SD	**67.9** ± 12.4 (146)	**69.1** ± 13.5 (145)	-0.24 (-0.80, 0.33)	0.410
		Change from Baseline	-3.75 (2.26) (146)	-4.06 (2.84) (145)		
	VISIT 7 / WEEK 24	Mean ± SD	**64.9** ± 12.2 (146)	**66.0** ± 13.2 (145)	-0.29 (-0.85, 0.28)	0.317
		Change from Baseline	-6.72 (3.09) (146)	-7.07 (3.91) (145)		
BMI	VISIT 2 / Baseline	Mean ± SD	**28.0** ± 4.5 (146)	**28.6** ± 5.3 (145)	NA	NA
		Change from Baseline	-	-		
	VISIT 5 / WEEK 12	Mean ± SD	**26.5** ± 4.2 (146)	**27.0** ± 5.0 (145)	-0.07 (-0.32, 0.18)	0.582
		Change from Baseline	-1.49 (0.93) (146)	-1.60 (1.18) (145)		
	VISIT 7 / WEEK 24	Mean ± SD	**25.4** ± 4.2 (146)	**25.9** ± 4.9 (145)	-0.11 (-0.35, 0.13)	0.381
		Change from Baseline	-2.62 (1.47) (146)	-2.77 (1.60) (145)		

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.
GLP-1 is a physiological hormone that has multiple actions on glucose, mediated by the GLP- 1 receptors.
The principal mechanism of protraction resulting in the long half-life of semaglutide is albumin binding, which results in decreased renal clearance and protection from metabolic degradation. Furthermore, semaglutide is stabilized against degradation by the DPP-4 enzyme.Semaglutide reduces blood glucose through a mechanism where it stimulates insulin secretion and lowers glucagon secretion, both in a glucose-dependent manner. Thus, when blood glucose is high, insulin secretion is stimulated, and glucagon secretion is inhibited. The mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase.

5.2 Pharmacokinetic Properties

Absorption

Absolute bioavailability of semaglutide is 89%. Maximum concentration of semaglutide is reached 1 to 3 days post dose. Similar exposure is achieved with subcutaneous administration of semaglutide in the abdomen, thigh, or upper arm.
In patients with type 2 diabetes, semaglutide exposure increases in a dose-proportional manner for once-weekly doses of 0.5 mg, 1 mg and 2 mg. Steady-state exposure is achieved following 4-5 weeks of once-weekly administration. In patients with type 2 diabetes, the mean population-PK estimated steady-state concentrations following once weekly subcutaneous administration of 0.5 mg and 1 mg semaglutide were approximately 65.0 ng/mL and 123.0 ng/mL, respectively. In the trial comparing semaglutide 1 mg and 2 mg, the mean steady state concentrations were 111.1 ng/mL and 222.1 ng/mL, respectively.

Distribution

The mean apparent volume of distribution of semaglutide following subcutaneous administration in patients with type 2 diabetes is approximately 12.5L. Semaglutide is extensively bound to plasma albumin (>99%).

Elimination

The apparent clearance of semaglutide in patients with type 2 diabetes is approximately 0.05 L/h. With an elimination half-life of approximately 1 week, semaglutide will be present in the circulation for about 5 weeks after the last dose.

Metabolism

The primary route of elimination for semaglutide is metabolism following proteolytic cleavage of the peptide backbone and sequential beta-oxidation of the fatty acid sidechain.

Excretion

The primary excretion routes of semaglutide-related material are via the urine and feces. Approximately 3% of the dose is excreted in the urine as intact semaglutide.

Specific Populations

Patients with Renal impairment

Renal impairment does not impact the pharmacokinetics of semaglutide in a clinically relevant manner. This was shown in a study with a single dose of 0.5 mg semaglutide in patients with different degrees of renal impairment (mild, moderate, severe, ESRD) compared with subjects with normal renal function. This was also shown for subjects with both type 2 diabetes and renal impairment based on data from clinical studies.

Patients with Hepatic impairment

Hepatic impairment does not have any impact on the exposure of semaglutide. The pharmacokinetics of semaglutide were evaluated in patients with different degrees of hepatic impairment (mild, moderate, severe) compared with subjects with normal hepatic function in a study with a single-dose of 0.5 mg semaglutide.

Pediatric Patients

Semaglutide has not been studied in pediatric patients.

Drug Interaction Studies

In vitro studies have shown very low potential for semaglutide to inhibit or induce CYP enzymes, and to inhibit drug transporters.
The delay of gastric emptying with semaglutide may influence the absorption of concomitantly administered oral medicinal products.
The potential effect of semaglutide on the absorption of co-administered oral medications was studied in trials at semaglutide 1 mg steady-state exposure.
No clinically relevant drug-drug interaction with semaglutide was observed based on the evaluated medications; therefore, no dose adjustment is required when co-administered with semaglutide. In a separate study, no apparent effect on the rate of gastric emptying was observed with semaglutide 2.4 mg.

6. NONCLINICAL PROPERTIES

6.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 2-year carcinogenicity study in CD-1 mice, subcutaneous doses of 0.3, 1 and 3 mg/kg/day [2-, 11-, and 30-fold the maximum recommended human dose (MRHD) of 2 mg/week, based on AUC] were administered to the males, and 0.1, 0.3 and 1 mg/kg/day (1-, 2-, and 7-fold MRHD) were administered to the females. A statistically significant increase in thyroid C-cell adenomas and a numerical increase in C-cell carcinomas were observed in males and females at clinically relevant exposures.In a 2-year carcinogenicity study in Sprague Dawley rats, subcutaneous doses of 0.0025, 0.01, 0.025 and 0.1 mg/kg/day were administered (below quantification, 0.2-, 0.5-, and 3-fold the exposure at the MRHD). A statistically significant increase in thyroid C-cell adenomas was observed in males and females at all dose levels, and a statistically significant increase in thyroid C-cell carcinomas was observed in males at ≥0.01 mg/kg/day, at clinically relevant exposures.

Human relevance of thyroid C-cell tumors in rats is unknown and could not be determined by clinical studies or nonclinical studies. Semaglutide was not mutagenic or clastogenic in a standard battery of genotoxicity tests (bacterial mutagenicity (Ames), human lymphocyte chromosome aberration, rat bone marrow micronucleus).

In a combined fertility and embryo-fetal development study in rats, subcutaneous doses of 0.01, 0.03 and 0.09 mg/kg/day (0.06-, 0.2-, and 0.6-fold the MRHD) were administered to male and female rats. Males were dosed for 4 weeks prior to mating, and females were dosed for 2 weeks prior to mating and throughout organogenesis until gestation Day 17. No effects were observed on male fertility. In females, an increase in estrus cycle length was observed at all dose levels, together with a small reduction in numbers of corpora lutea at≥0.03mg/kg/day. These effects were likely an adaptive response secondary to the pharmacological effect of semaglutide on food consumption and body weight.

7. PHARMACEUTICAL PARTICULARS

7.1 Incompatibilities

None

7.2 Packing Information

One mono carton contains 1 pen with 3ml prefilled cartridge along with needles.

7.3 Shelf life

Refer Pack

7.4. Storage and Handling Instructions

Long-term Storage (Unopened Pen)

- **Store in a refrigerator between 2°C to 8°C. Do not freeze.**
- Do not store in the freezer or directly adjacent to the refrigerator cooling element.
- Do not freeze; do not use the product if it has been frozen.

In-Use Storage (After First Use)

- After first use, the pen can be stored for 56 days at a temperature of 15°C to 30°C or in a refrigerator at 2°C to 8°C. Do not freeze.
- Discard the pen after 56 days, even if it still contains product.

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. Counsel patients to report symptoms of thyroid tumors (e.g., a lump in the neck, hoarseness, dysphagia, or dyspnea) to their physician.

Pancreatitis

Inform patients of the potential risk for pancreatitis. Instruct patients to discontinue semaglutide promptly and contact their physician if pancreatitis is suspected (severe abdominal pain that may radiate to the back, and which may or may not be accompanied by vomiting).

Diabetic Retinopathy Complications

Inform patients to contact 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.

Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin

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

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. In each case, inform patients to resume their regular once weekly dosing schedule.

9. Manufactured and packed by

MSN Laboratories Pvt. Ltd.
At: M/S. OneSource Speciality Pharma Limited,
Plot No. 2-D1, Obadenahalli, Doddaballapura,
3rd Phase, Industrial Area, Doddaballapura Taluk,
Bengaluru Rural – 561203, India.

10. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

KTK/28A/0925/2024
29/07/2024

11. DATE OF REVISION

March 2026

Marketed by:

TORRENT PHARMA
TORRENT PHARMACEUTICALS LTD.
Indrad- 382721, Dist. Mehsana, India

8107988-9091

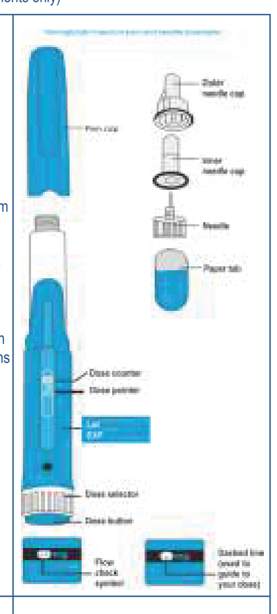
TM - Trademark under registration.

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)

- **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 prefilled, single-patient-use, diala-dose pen.** It contains 2 mg of semaglutide, and you can select doses of 0.25 mg or 0.5 mg. Each prefilled pen contains 4 doses of 0.25 mg and 2 doses of 0.5 mg or contains 4 doses of 0.5 mg.
- Your pen is made to be used with **BD Ultra-Fine™** disposable needles up to a length of 8 mm.
- BD Ultra-FineTM 32G 4 mm disposable needles are included with your semaglutide injection pen.
- **Always use a new needle for each injection.**

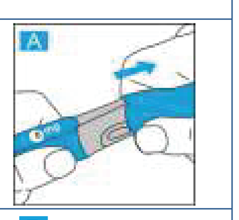
Supplies you will need to give your semaglutide injection:

- Semaglutide injection pen
- a new BD Ultra-FineTM needle

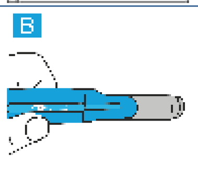


Step 1.
Prepare your pen with a new needle

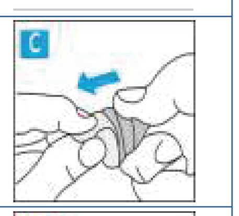
- **Wash your hands with soap and water.**
- **Check the name and colored label** of your pen, to make sure that it contains semaglutide injection. This is especially important if you take more than 1 type of medicine.
- **Pull off the pen cap.**



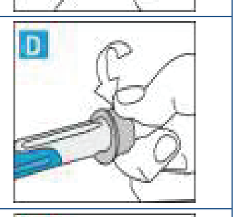
- **Check that the semaglutide injection medicine in your pen is clear and colorless.** Look through the pen window. If semaglutide injection looks cloudy or contains particles, do not use the pen.



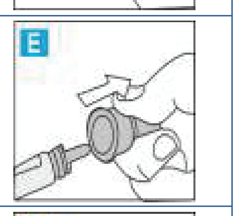
- **Take a new needle,** and tear off the paper tab. **Do not attach a new needle** to your pen until you are ready to give your injection.



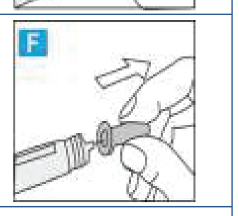
- **Push the needle straight onto the pen. Turn until it is on tight.**



- **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.



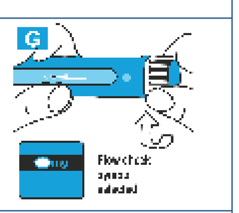
- **Pull off the inner needle cap** and throw it away. A drop of semaglutide injection may appear at the needle tip. This is normal, but you must still check the semaglutide injection flow if you use a new pen for the first time.



⚠ **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

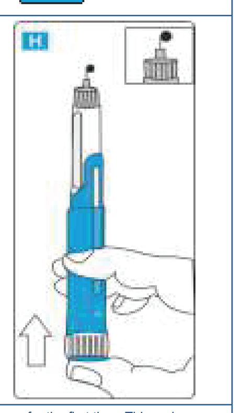
- Check the semaglutide injection flow **before the first injection with each new pen only.** If your semaglutide injection pen is already in use, go to Step 3 "Select your dose".
- Turn the dose selector **until the dose counter shows the flow check symbol (▬▬◂)**



- 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.

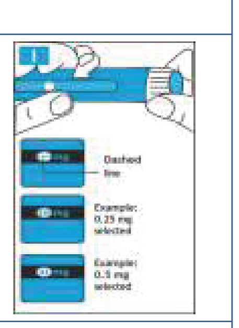
A small drop may remain at the needle tip, but it will not be injected.
Only check the semaglutide injection flow before your first injection with each new pen.

Step 3.
Select your dose

- **Turn the dose selector until the dose counter stops and shows your dose (0.25 mg or 0.5 mg).**

  The dashed line in the dose counter will (⁝) guide you to your dose.

  Make sure you know the dose of semaglutide injection you should use. If you select the wrong dose, you can turn the dose selector forward or backwards to the correct dose.



⚠ **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 0.25 mg or 0.5 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 how many mg you select for each dose.**

You can select 0.25 mg or 0.5 mg for each dose. When your pen contains less than 0.5 or 0.25 mg, the dose counter stops before 0.5 mg or 0.25 mg is shown.

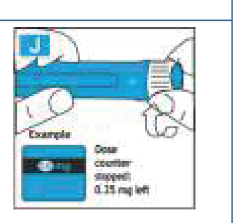
The dose selector clicks differently when turned forward or backward. Do not count the pen clicks.

How much semaglutide injection is left?

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

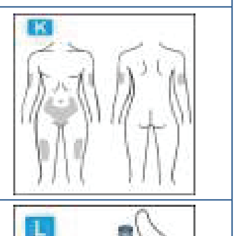
  Turn the dose selector until the dose counter stops.
  - If it shows 0.5, at least 0.5 mg is left in your pen. If the dose counter stops before 0.5 mg, there is not enough semaglutide injection left for a full dose of 0.5 mg
  - If it shows 0.25, at least 0.25 mg is left in your pen. If the dose counter stops before 0.25 mg, there is not enough semaglutide injection left for a full dose of 0.25 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.

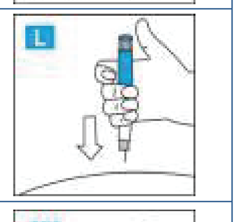


Step 4.
Inject your dose

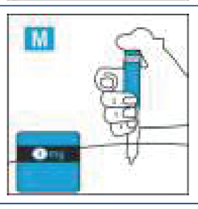
- Choose your injection site and wipe the skin with an alcohol swab. Let the injection site dry before you inject your dose (See Figure **K**).



- **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.**



4470

PRODUCT NAME	:	SEMALIX 8	COUNTRY : Domestic P2P	LOCATION : MSN Lab.		SUPERSEDES A/W NO. : Nil		
ITEM / PACK	:	PIL	NO. OF COLORS : 4	SUBSTRATE :				
DESIGN STYLE	:	Front	PANTONE SHADE NOS. :	REMARK :				
CODE	:	8107988-9093	CMYK	Activities	Department	Name	Signature	Date
DIMENSIONS (MM)	:	750 x 340 mm		Prepared By	Pkg.Dev			
ART WORK SIZE	:	S/S		Reviewed By	Pkg.Dev			
DATE	:	03-03-2026		Approved By	CR			
				Approved By	Quality			
				Approved By	Quality			

This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.

340 mm

750 mm

- **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.

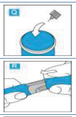
How to identify a blocked or damaged needle?
- If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.
- If this happens you have not received any semaglutide injection even though the dose counter has moved from the original 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:
  - o made of a heavy-duty plastic
  - o can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
  - o upright and stable during use
  - o leak-resistant
  - o 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.
- Safety disposal of semaglutide injection that is out of date or no longer needed.

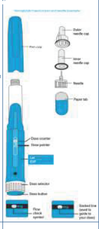
⚠ **Important**
- Caregivers must **be very careful when handling used needles** to prevent accidental needle stick injuries and prevent passing (transmission) of infection.
- Never use a syringe to withdraw semaglutide injection from your pen.
- **Always carry an extra pen and new needles** with you, 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 2°C to 8°C.
- Store your pen in use for 56 days at room temperature between 15°C to 30°C or in a refrigerator between 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-gloo-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 prefilled, single-patient-use, dial-a-dose pen.** It contains 2 mg of semaglutide, and you can select doses of 2 mg. Each prefilled 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

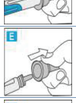
Step 1.
Prepare your pen with a new needle
- **Wash your hands with soap and water.**
- **Check the name and colored label** of your pen, to make sure that it contains semaglutide injection. This is especially important if you take more than 1 type of medicine.
- **Pull off the pen cap.**

- **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.

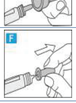
- **Take a new needle,** and tear off the paper tab. **Do not attach a new needle** to your pen until you are ready to give your injection.

- **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.



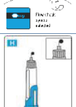
⚠ **Always use a new needle for each injection.** This will reduce the risk of contamination, infection, leakage of semaglutide injection, and blocked needles leading to the wrong dose.
Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious 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.



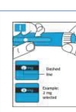
⚠ **Always make sure that a drop appears** at the needle tip before you use a new pen for the first time. This makes sure that semaglutide injection flows.

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 ⊟ 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:
  - o made of a heavy-duty plastic
  - o can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
  - o upright and stable during use
  - o leak-resistant
  - o 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.
- Safety disposal 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 2°C to 8°C.
- Store your pen in use for 56 days at room temperature between 15°C to 30°C or in a refrigerator between 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-gloo-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 prefilled, single-patient-use, dial-a-dose pen.** It contains 4 mg of semaglutide, and you can select doses of 1 mg. Each prefilled pen contains 4 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

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.

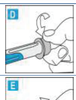
  Do not use the pen if a drop of semaglutide injection still does not appear.

⚠ **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 ⊟ 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.
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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:
  - o made of a heavy-duty plastic
  - o can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
  - o upright and stable during use
  - o leak-resistant
  - o properly labeled to warn of hazardous waste inside the container
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- 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.
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- **Do not wash, soak, or lubricate your pen.** If necessary, clean it with mild detergent on a moistened cloth.

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- 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.

4470

PRODUCT NAME	:	SEMALIX 8	**COUNTRY :** Domestic P2P	**LOCATION :** MSN Lab.		**SUPERSEDES A/W NO. :**	Nil	
ITEM / PACK	:	PIL	**NO. OF COLORS :** 4	**SUBSTRATE :**				
DESIGN STYLE	:	Back	**PANTONE SHADE NOS. :**	**REMARK :**				
CODE	:	8107988-9093	**CMYK**	**Activities**	**Department**	**Name**	**Signature**	**Date**
DIMENSIONS (MM)	:	750 x 340 mm		Prepared By	**Pkg.Dev**			
ART WORK SIZE	:	S/S		Reviewed By	**Pkg.Dev**			
DATE	:	03-03-2026		Approved By	**CR**			
				Approved By	**Quality**			
				Approved By	**Quality**			

This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.