ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 2.5 mg solution for injection in pre-filled pen
Mounjaro 5 mg solution for injection in pre-filled pen
Mounjaro 7.5 mg solution for injection in pre-filled pen
Mounjaro 10 mg solution for injection in pre-filled pen
Mounjaro 12.5 mg solution for injection in pre-filled pen
Mounjaro 15 mg solution for injection in pre-filled pen

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Mounjaro 2.5 mg solution for injection in pre-filled pen

Each pre-filled pen contains 2.5 mg of tirzepatide in 0.5 ml solution.

Mounjaro 5 mg solution for injection in pre-filled pen

Each pre-filled pen contains 5 mg of tirzepatide in 0.5 ml solution.

Mounjaro 7.5 mg solution for injection in pre-filled pen

Each pre-filled pen contains 7.5 mg of tirzepatide in 0.5 ml solution.

Mounjaro 10 mg solution for injection in pre-filled pen

Each pre-filled pen contains 10 mg of tirzepatide in 0.5 ml solution.

Mounjaro 12.5 mg solution for injection in pre-filled pen

Each pre-filled pen contains 12.5 mg of tirzepatide in 0.5 ml solution.

Mounjaro 15 mg solution for injection in pre-filled pen

Each pre-filled pen contains 15 mg of tirzepatide in 0.5 ml solution.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless to slightly yellow solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

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

For study results with respect to combinations, effects on glycaemic control and the populations studied, see sections 4.4, 4.5 and 5.1.

4.2 Posology and method of administration

Posology

The starting dose of tirzepatide is 2.5 mg once weekly. After 4 weeks, the dose should be increased to 5 mg once weekly. If needed, dose increases can be made in 2.5 mg increments after a minimum of 4 weeks on the current dose.

The recommended maintenance doses are 5, 10 and 15 mg.

The maximum dose is 15 mg once weekly.

When tirzepatide is added to existing metformin and/or sodium-glucose co-transporter 2 inhibitor (SGLT2i) therapy, the current dose of metformin and/or SGLT2i can be continued.

When tirzepatide is added to existing therapy of a sulphonylurea and/or insulin, a reduction in the dose of sulphonylurea or insulin may be considered to reduce the risk of hypoglycaemia. Blood glucose self-monitoring is necessary to adjust the dose of sulphonylurea and insulin. A stepwise approach to insulin reduction is recommended (see sections 4.4 and 4.8).

Missed doses

If a dose is missed, it should be administered as soon as possible within 4 days after the missed dose. If more than 4 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.

Changing the dosing schedule

The day of weekly administration can be changed, if necessary, as long as the time between two doses is at least 3 days.

Special populations

Elderly, gender, race, ethnicity or body weight
No dose adjustment is needed based on age, gender, race, ethnicity or body weight (see sections 5.1 and 5.2).

Renal impairment
No dose adjustment is required for patients with renal impairment including end stage renal disease (ESRD). Experience with the use of tirzepatide in patients with severe renal impairment and ESRD is limited. Caution should be exercised when treating these patients with tirzepatide (see section 5.2).

Hepatic impairment
No dose adjustment is required for patients with hepatic impairment. Experience with the use of tirzepatide in patients with severe hepatic impairment is limited. Caution should be exercised when treating these patients with tirzepatide (see section 5.2).

Paediatric population
The safety and efficacy of tirzepatide in children aged less than 18 years have not yet been established. No data are available.

Method of administration

Mounjaro is to be injected subcutaneously in the abdomen, thigh or upper arm.

The dose can be administered at any time of day, with or without meals.

Injection sites should be rotated with each dose. If a patient also injects insulin, they should inject Mounjaro into a different injection site.

Patients should be advised to read the instructions for use included with the package leaflet carefully before administering the medicinal product.

For further information before administration see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Acute pancreatitis

Tirzepatide 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 tirzepatide.

Patients should be informed of the symptoms of acute pancreatitis. If pancreatitis is suspected, tirzepatide should be discontinued. If the diagnosis of pancreatitis is confirmed, tirzepatide 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 (see section 4.8).

Hypoglycaemia

Patients receiving tirzepatide in combination with an insulin secretagogue (for example, a sulphonylurea) or insulin may have an increased risk of hypoglycaemia. The risk of hypoglycaemia may be lowered by a reduction in the dose of the insulin secretagogue or insulin (see sections 4.2 and 4.8).

Gastrointestinal effects

Tirzepatide has been associated with gastrointestinal adverse reactions, which include nausea, vomiting, and diarrhoea (see section 4.8). These adverse reactions may lead to dehydration, which could lead to a deterioration in renal function including acute renal failure. Patients treated with tirzepatide should be advised of the potential risk of dehydration, due to the gastrointestinal adverse reactions and take precautions to avoid fluid depletion and electrolyte disturbances. This should particularly be considered in the elderly, who may be more susceptible to such complications.

Severe gastrointestinal disease

Tirzepatide has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and should be used with caution in these patients.

Diabetic retinopathy

Tirzepatide has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy or diabetic macular oedema, and should be used with caution in these patients with appropriate monitoring

Elderly

Only very limited data are available from patients aged ≥ 85 years.

Sodium content

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

4.5 Interaction with other medicinal products and other forms of interaction

Tirzepatide delays gastric emptying and thereby has the potential to impact the rate of absorption of concomitantly administered oral medicinal products. This effect, resulting in decreased C_{max} and a delayed t_{max}, is most pronounced at the time of tirzepatide treatment initiation.

Based on the results from a study with paracetamol, which was used as a model medicinal product to evaluate the effect of tirzepatide on gastric emptying, no dose adjustments are expected to be required for most concomitantly administered oral medicinal products. However, it is recommended to monitor patients on oral medicinal products with a narrow therapeutic index (e.g., warfarin, digoxin), especially at initiation of -tirzepatide treatment and following dose increase. The risk of delayed effect should also be considered for oral medicinal products for which a rapid onset of effect is of importance.

Paracetamol

Following a 5 mg single dose of tirzepatide, the maximum plasma concentration (C_{max}) of paracetamol was reduced by 50 %, and the median (t_{max}) was delayed by 1 hour. The effect of tirzepatide on the oral absorption of paracetamol is dose and time dependent. At low doses (0.5 and 1.5 mg), there was only a minor change in paracetamol exposure. After four consecutive weekly doses of tirzepatide (5/5/8/10 mg), no effect on the paracetamol Cmax and tmax was observed. The overall exposure (AUC) was not influenced. No dose adjustment of paracetamol is necessary when administered with tirzepatide.

Oral contraceptives

Administration of a combination oral contraceptive (0.035 mg ethinyl estradiol plus 0.25 mg norgestimate, a prodrug of norelgestromin) in the presence of a single dose of tirzepatide (5 mg) resulted in a reduction of oral contraceptive C_{max} and area under the curve (AUC). Ethinyl estradiol C_{max} was reduced by 59 % and AUC by 20 % with a delay in t_{max} of 4 hours. Norelgestromin C_{max} was reduced by 55 % and AUC by 23 % with a delay in t_{max} of 4.5 hours. Norgestimate C_{max} was reduced by 66 %, and AUC by 20 % with a delay in t_{max} of 2.5 hours. This reduction in exposure after a single dose of tirzepatide is not considered clinically relevant. No dose adjustment of oral contraceptives is required.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or a limited amount of data from the use of tirzepatide in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). Tirzepatide is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breast-feeding

It is unknown whether tirzepatide is excreted in human milk. A risk to the newborn/infant cannot be excluded.

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from tirzepatide therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

The effect of tirzepatide on fertility in humans is unknown.

Animal studies with tirzepatide did not indicate direct harmful effects with respect to fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

Tirzepatide has no or negligible influence on the ability to drive or use machines. When tirzepatide is used in combination with a sulphonylurea or insulin, patients should be advised to take precautions to avoid hypoglycaemia while driving and using machines (see section 4.4).

4.8 Undesirable effects

Summary of safety profile

In 7 completed phase 3 studies, 5119 patients were exposed to tirzepatide alone or in combination with other glucose lowering medicinal products. The most frequently reported adverse reactions were gastrointestinal disorders, including nausea (very common), diarrhoea (very common) and vomiting (common). In general, these reactions were mostly mild or moderate in severity and occurred more often during dose escalation and decreased over time (see sections 4.2, and 4.4).

Tabulated list of adverse reactions

The following related adverse reactions from clinical studies are listed below by system organ class and in order of decreasing incidence (very common: ≥ 1/10; common: ≥ 1/100 to < 1/10; uncommon: ≥ 1/1 000 to < 1/100; rare: ≥ 1/10 000 to < 1/1 000; very rare: < 1/10 000). Within each incidence grouping, adverse reactions are presented in order of decreasing frequency.

Table 1. Adverse reactions

System organ class	Very common	Common	Uncommon
Immune system disorders		Hypersensitivity reactions	
Metabolism and nutrition disorders	Hypoglycaemia* when used with sulphonylurea or insulin	Hypoglycaemia* when used with metformin and SGLT2i, decreased appetite	Hypoglycaemia* when used with metformin, weight decreased
Gastrointestinal disorders	Nausea, diarrhoea	Abdominal pain, vomiting, dyspepsia, constipation, abdominal distention, eructation, flatulence, gastroesophageal reflux disease	Cholelithiasis, acute pancreatitis
General disorders and administration site conditions		Fatigue[†], injection site reactions	
Investigations		Heart rate increased, lipase increased, amylase increased	Blood calcitonin increased

*Hypoglycaemia defined below.
[†]Fatigue includes the terms fatigue, asthenia, malaise, and lethargy.

Description of selected adverse reactions

Hypersensitivity reactions

Hypersensitivity reactions have been reported with tirzepatide in the pool of placebo-controlled trials, sometimes severe (e.g., urticaria and eczema); hypersensitivity reactions were reported in 3.2 % of tirzepatide-treated patients compared to 1.7 % of placebo-treated patients.

Hypoglycaemia

Clinically significant hypoglycaemia (blood glucose < 3.0 mmol/L (< 54 mg/dL) or severe hypoglycaemia (requiring the assistance of another person)) occurred in 10 to 14 % (0.14 to 0.16 events/patient year) of patients when tirzepatide was added to sulphonylurea and in 14 to 19 % (0.43 to 0.64 events/patient year) of patients when tirzepatide was added to basal insulin.

The rate of clinically significant hypoglycaemia when tirzepatide was used as monotherapy or when added to other oral antidiabetic medicinal products was up to 0.04 events/patient year (see table 1 and sections 4.2, 4.4 and 5.1).

In phase 3 clinical studies, 10 (0.2 %) patients reported 12 episodes of severe hypoglycaemia. Of these 10 patients, 5 (0.1 %) were on a background of insulin glargine or sulphonylurea who reported 1 episode each.

Gastrointestinal adverse reactions

In the placebo-controlled phase 3 studies, gastrointestinal disorders were dose-dependently increased for tirzepatide 5 mg (37.1 %), 10 mg (39.6 %) and 15 mg (43.6 %) compared with placebo (20.4 %). Nausea occurred in 12.2 %, 15.4 % and 18.3 % versus 4.3 % and diarrhoea in 11.8 %, 13.3 % and 16.2 % versus 8.9 % for tirzepatide 5 mg, 10 mg and 15 mg versus placebo. Gastrointestinal adverse

reactions were mostly mild (74 %) or moderate (23.3 %) in severity. The incidence of nausea, vomiting, and diarrhoea was higher during the dose escalation period and decreased over time.

More subjects in the tirzepatide 5 mg (3.0 %), 10 mg (5.4 %) and 15 mg (6.6 %) groups compared to the placebo group (0.4 %) discontinued permanently due to the gastrointestinal event.

Immunogenicity

5 025 tirzepatide-treated patients in the phase 3 clinical studies were assessed for anti-drug antibodies (ADAs). Of these, 51.1 % developed treatment-emergent (TE) ADAs during the on-treatment period. In 38.3 % of the assessed patients, TE ADAs were persistent (ADAs present for a period of 16-weeks or greater). 1.9 % and 2.1 % had neutralizing antibodies against tirzepatide activity on the glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptors, respectively and 0.9 % and 0.4 % had neutralising antibodies against native GIP and GLP-1, respectively. There was no evidence of an altered pharmacokinetic profile or an impact on efficacy and safety of tirzepatide associated with the development of ADAs.

Heart rate

In the placebo-controlled phase 3 studies, treatment with tirzepatide resulted in a maximum mean increase in heart rate of 3 to 5 beats per minute. The maximum mean increase in heart rate in placebo-treated patients was 1 beat per minute.

The incidence of patients who had a change of baseline heart rate of > 20 bpm for 2 or more consecutive visits was 2.1 %, 3.8 % and 2.9 %, for tirzepatide 5 mg, 10 mg and 15 mg, respectively, compared with 2.1 % for placebo.

Small mean increases in PR interval were observed with tirzepatide when compared to placebo (mean increase of 1.4 to 3.2 msec and mean decrease of 1.4 msec respectively). No difference in arrythmia and cardiac conduction disorder treatment emergent events were observed between tirzepatide 5 mg, 10 mg, 15 mg and placebo (3.8 %, 2.1 %, 3.7 % and 3 % respectively).

Injection site reactions

In the placebo-controlled phase 3 studies, injection site reactions were increased for tirzepatide (3.2 %) compared with placebo (0.4 %).

Overall, in the phase 3 studies, the most common signs and symptoms of injection site reactions were erythema and pruritus. The maximum severity of injection site reactions for patients was mild (90 %) or moderate (10 %). No injection site reactions were serious.

Pancreatic enzymes

In the placebo-controlled phase 3 studies, treatment with tirzepatide resulted in mean increases from baseline in pancreatic amylase of 33 % to 38 % and lipase of 31 % to 42 %. Placebo treated patients had an increase from baseline in amylase of 4 % and no changes were observed in lipase.

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. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. Patients may experience gastrointestinal adverse reactions including nausea. There is no specific antidote for overdose of tirzepatide. A prolonged period of observation and treatment of these symptoms may be necessary, taking into account the half-life of tirzepatide (approximately 5 days).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in diabetes, blood glucose lowering drugs, excl. insulins, ATC code: not yet assigned

Mechanism of action

Tirzepatide is a long acting dual GIP and GLP-1 receptor agonist. Both receptors are present on the pancreatic α and β endocrine cells, brain, heart, vasculature, immune cells (leukocytes), gut and kidney. GIP receptors are also present on adipocytes.

Tirzepatide is highly selective to human GIP and GLP-1 receptors. Tirzepatide has high affinity to both the GIP and GLP-1 receptors. The activity of tirzepatide on the GIP receptor is similar to native GIP hormone. The activity of tirzepatide on the GLP-1 receptor is lower compared to native GLP-1 hormone.

Glycaemic control

Tirzepatide improves glycaemic control by lowering fasting and postprandial glucose concentrations in patients with type 2 diabetes through several mechanisms.

Pharmacodynamic effects

Insulin secretion

Tirzepatide increases pancreatic β-cell glucose sensitivity. It enhances first- and second-phase insulin secretion in a glucose dependent manner.

In a hyperglycaemic clamp study in patients with type 2 diabetes, tirzepatide was compared to placebo and the selective GLP-1 receptor agonist semaglutide 1 mg for insulin secretion. Tirzepatide 15 mg enhanced the first and second-phase insulin secretion rate by 466 % and 302 % from baseline, respectively. There was no change in first- and second-phase insulin secretion rate for placebo.

Insulin sensitivity

Tirzepatide improves insulin sensitivity.

Tirzepatide 15 mg improved whole body insulin sensitivity by 63 %, as measured by M-value, a measure of glucose tissue uptake using hyperinsulinemic euglycaemic clamp. The M-value was unchanged for placebo .

Tirzepatide lowers body weight in patients with type 2 diabetes, which may contribute to improvement in insulin sensitivity. Reduced food intake with tirzepatide contributes to body weight loss. The body weight reduction is mostly due to reduced fat mass.

Glucagon concentration

Tirzepatide reduced the fasting and postprandial glucagon concentrations in a glucose dependent manner. Tirzepatide 15 mg reduced fasting glucagon concentration by 28 % and glucagon AUC after a mixed meal by 43 %, compared with no change for placebo.

Gastric emptying

Tirzepatide delays gastric emptying which may slow post meal glucose absorption and can lead to a beneficial effect on postprandial glycaemia. Tirzepatide induced delay in gastric emptying diminishes over time.

Clinical efficacy and safety

The safety and efficacy of tirzepatide were evaluated in five global randomised, controlled, phase 3 studies (SURPASS 1-5) assessing glycaemic control as the primary objective. The studies involved 6 263 treated patients with type 2 diabetes (4 199 treated with tirzepatide). The secondary objectives included body weight, fasting serum glucose (FSG) and proportion of patients reaching target HbA1c. All five phase 3 studies assessed tirzepatide 5 mg, 10 mg and 15 mg. All patients treated with tirzepatide started with 2.5 mg for 4 weeks. Then the dose of tirzepatide was increased by 2.5 mg every 4 weeks until they reached their assigned dose.

Across all studies, treatment with tirzepatide demonstrated sustained, statistically significant and clinically meaningful reductions from baseline in HbA1c as the primary objective compared to either placebo or active control treatment (semaglutide, insulin degludec and insulin glargine) for up to 1 year. In 1 study these effects were sustained for up to 2 years. Statistically significant and clinically meaningful reductions from baseline in body weight were also demonstrated. Results from the phase 3 studies are presented below based on the on-treatment data without rescue therapy in the modified intent-to-treat (mITT) population consisting of all randomly assigned patients who were exposed to at least 1 dose of study treatment, excluding patients discontinuing study treatment due to inadvertent enrolment.

SURPASS 1 – Monotherapy

In a 40 week double blind placebo-controlled study, 478 patients with inadequate glycaemic control with diet and exercise, were randomised to tirzepatide 5 mg, 10 mg or 15 mg once weekly or placebo. Patients had a mean age of 54 years and 52 % were men. At baseline the patients had a mean duration of diabetes of 5 years and the mean BMI was 32 kg/m^2.

Table 2. SURPASS 1: Results at week 40

		Tirzepatide 5 mg	Tirzepatide 10 mg	Tirzepatide 15 mg	Placebo
mITT population (n)		121	121	120	113
HbA_{1c} (%)	Baseline (mean)	7.97	7.88	7.88	8.08
	Change from baseline	-1.87##	-1.89##	-2.07##	+0.04
	Difference from placebo [95 % CI]	-1.91** [-2.18, -1.63]	-1.93** [-2.21, -1.65]	-2.11** [-2.39, -1.83]	-
HbA_{1c} (mmol/mol)	Baseline (mean)	63.6	62.6	62.6	64.8
	Change from baseline	-20.4##	-20.7##	-22.7##	+0.4
	Difference from placebo [95 % CI]	-20.8** [-23.9, -17.8]	-21.1** [-24.1, -18.0]	-23.1** [-26.2, -20.0]	-
Patients (%) achieving HbA_{1c}	< 7 %	86.8**	91.5**	87.9**	19.6
	≤ 6.5 %	81.8††	81.4††	86.2††	9.8
	< 5.7 %	33.9**	30.5**	51.7**	0.9
FSG (mmol/L)	Baseline (mean)	8.5	8.5	8.6	8.6
	Change from baseline	-2.4##	-2.6##	-2.7##	+0.7#
	Difference from placebo [95 % CI]	-3.13** [-3.71, -2.56]	-3.26** [-3.84, -2.69]	-3.45** [-4.04, -2.86]	-
FSG (mg/dL)	Baseline (mean)	153.7	152.6	154.6	155.2
	Change from baseline	-43.6##	-45.9##	-49.3##	+12.9#
	Difference from placebo [95 % CI]	-56.5** [-66.8, -46.1]	-58.8** [-69.2, -48.4]	-62.1** [-72.7, -51.5]	-
Body weight (kg)	Baseline (mean)	87.0	85.7	85.9	84.4
	Change from baseline	-7.0##	-7.8##	-9.5##	-0.7
	Difference from placebo [95 % CI]	-6.3** [-7.8, -4.7]	-7.1** [-8.6, -5.5]	-8.8** [-10.3, -7.2]	-
Patients (%) achieving weight loss	≥ 5 %	66.9††	78.0††	76.7††	14.3
	≥ 10 %	30.6††	39.8††	47.4††	0.9
	≥ 15 %	13.2†	17.0†	26.7†	0.0

*p < 0.05, ** p < 0.001 for superiority, adjusted for multiplicity.
†p < 0.05, ††p < 0.001 compared to placebo, not adjusted for multiplicity.
#p < 0.05, ## p < 0.001 compared to baseline, not adjusted for multiplicity.

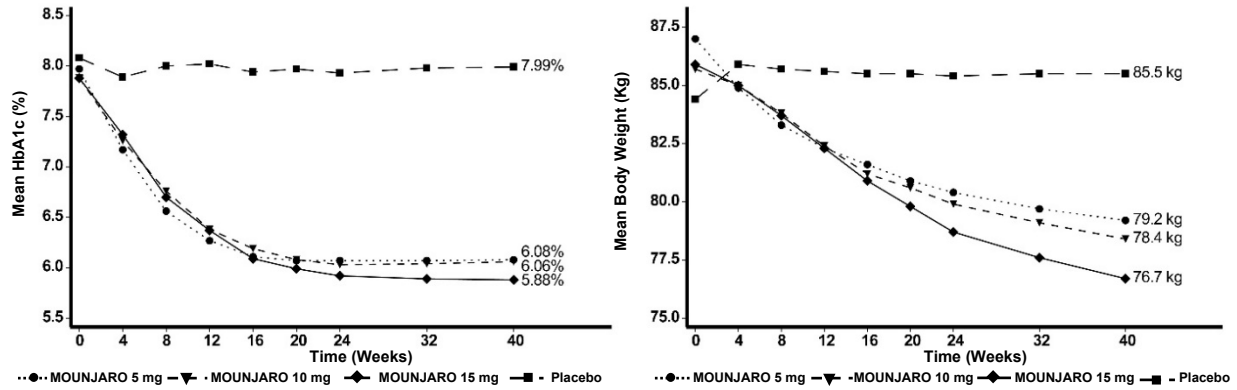

Figure 1. Mean HbA_{1c} (%) and mean body weight (kg) from baseline to week 40

SURPASS 2 - Combination therapy with metformin

In a 40 week active-controlled open-label study, (double-blind with respect to tirzepatide dose assignment) 1 879 patients were randomised to tirzepatide 5 mg, 10 mg or 15 mg once weekly or

semaglutide 1 mg once weekly, all in combination with metformin. Patients had a mean age of 57 years and 47 % were men. At baseline the patients had a mean duration of diabetes of 9 years and the mean BMI was 34 kg/m^2.

Table 3. SURPASS 2: Results at week 40

		Tirzepatide 5 mg	Tirzepatide 10 mg	Tirzepatide 15 mg	Semaglutide 1 mg
mITT population (n)		470	469	469	468
HbA_{1c} (%)	Baseline (mean)	8.33	8.31	8.25	8.24
	Change from baseline	-2.09$^{\#\#}$	-2.37$^{\#\#}$	-2.46$^{\#\#}$	-1.86$^{\#\#}$
	Difference from semaglutide [95 % CI]	-0.23** [-0.36, -0.10]	-0.51** [-0.64, -0.38]	-0.60** [-0.73, -0.47]	-
HbA_{1c} (mmol/mol)	Baseline (mean)	67.5	67.3	66.7	66.6
	Change from baseline	-22.8$^{\#\#}$	-25.9$^{\#\#}$	-26.9$^{\#\#}$	-20.3$^{\#\#}$
	Difference from semaglutide [95 % CI]	-2.5** [-3.9, -1.1]	-5.6** [-7.0, -4.1]	-6.6** [-8.0, -5.1]	N/A
Patients (%) achieving HbA_{1c}	< 7 %	85.5*	88.9**	92.2**	81.1
	≤ 6.5 %	74.0†	82.1††	87.1††	66.2
	< 5.7 %	29.3††	44.7**	50.9**	19.7
FSG (mmol/L)	Baseline (mean)	9.67	9.69	9.56	9.49
	Change from baseline	-3.11$^{\#\#}$	-3.42$^{\#\#}$	-3.52$^{\#\#}$	-2.70$^{\#\#}$
	Difference from semaglutide [95 % CI]	-0.41† [-0.65, -0.16]	-0.72†† [-0.97, -0.48]	-0.82†† [-1.06, -0.57]	-
FSG (mg/dL)	Baseline (mean)	174.2	174.6	172.3	170.9
	Change from baseline	-56.0$^{\#\#}$	-61.6$^{\#\#}$	-63.4$^{\#\#}$	-48.6$^{\#\#}$
	Difference from semaglutide [95 % CI]	-7.3† [-11.7, -3.0]	-13.0†† [-17.4, -8.6]	-14.7†† [-19.1, -10.3]	-
Body weight (kg)	Baseline (mean)	92.6	94.9	93.9	93.8
	Change from baseline	-7.8$^{\#\#}$	-10.3$^{\#\#}$	-12.4$^{\#\#}$	-6.2$^{\#\#}$
	Difference from semaglutide [95 % CI]	-1.7** [-2.6, -0.7]	-4.1** [-5.0, -3.2]	-6.2** [-7.1, -5.3]	-
Patients (%) achieving weight loss	≥ 5 %	68.6†	82.4††	86.2††	58.4
	≥ 10 %	35.8††	52.9††	64.9††	25.3
	≥ 15 %	15.2†	27.7††	39.9††	8.7

$^{*}p < 0.05$, ** $p < 0.001$ for superiority, adjusted for multiplicity.

$^{\dagger}p < 0.05$, $^{\dagger\dagger}p < 0.001$ compared to semaglutide 1 mg, not adjusted for multiplicity.

$^{\#}p < 0.05$, $^{\#\#}p < 0.001$ compared to baseline, not adjusted for multiplicity.

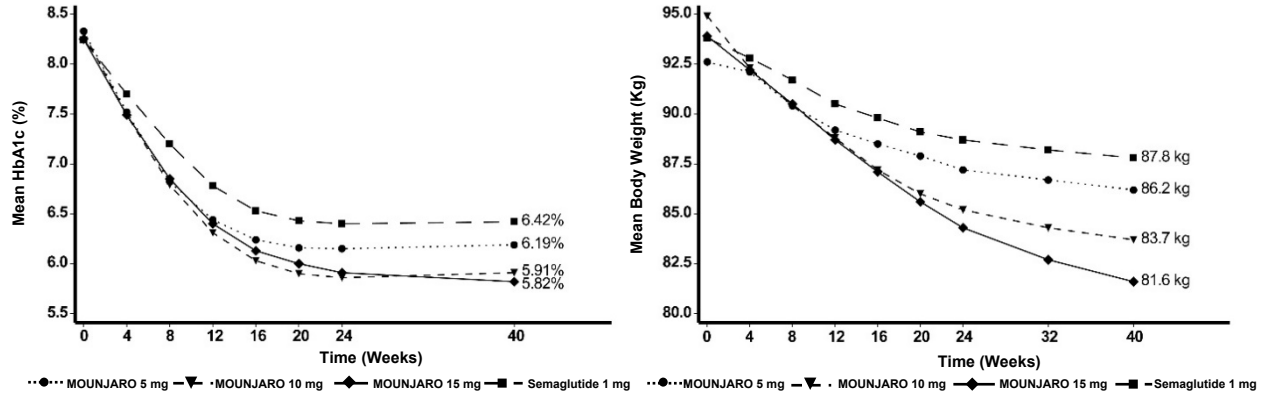

Figure 2. Mean HbA_{1c} (%) and mean body weight (kg) from baseline to week 40

SURPASS 3 - Combination therapy with metformin, with or without SGLT2i

In a 52 week active-controlled open-label study, 1 444 patients were randomised to tirzepatide 5 mg, 10 mg or 15 mg once weekly or insulin degludec, all in combination with metformin with or without a SGLT2i. 32 % of patients were using SGLT2i at baseline. At baseline the patients had a mean duration of diabetes of 8 years, a mean BMI of 34 kg/m^2, a mean age of 57 years and 56 % were men.

Patients treated with insulin degludec started at a dose of 10 U/day which was adjusted using an algorithm for a target fasting blood glucose of < 5 mmol/L. The mean dose of insulin degludec at week 52 was 49 units/day.

Table 4. SURPASS 3: Results at week 52

		Tirzepatide 5 mg	Tirzepatide 10 mg	Tirzepatide 15 mg	Titrated insulin degludec
mITT population (n)		358	360	358	359
HbA_{1c} (%)	Baseline (mean)	8.17	8.19	8.21	8.13
	Change from baseline	-1.93$^{\#\#}$	-2.20$^{\#\#}$	-2.37$^{\#\#}$	-1.34$^{\#\#}$
	Difference from insulin degludec [95 % CI]	-0.59** [-0.73, -0.45]	-0.86** [-1.00, -0.72]	-1.04** [-1.17, -0.90]	-
HbA_{1c} (mmol/mol)	Baseline (mean)	65.8	66.0	66.3	65.4
	Change from baseline	-21.1$^{\#\#}$	-24.0$^{\#\#}$	-26.0$^{\#\#}$	-14.6$^{\#\#}$
	Difference from insulin degludec [95 % CI]	-6.4** [-7.9, -4.9]	-9.4** [-10.9, -7.9]	-11.3** [-12.8, -9.8]	-
Patients (%) achieving HbA_{1c}	< 7 %	82.4**	89.7**	92.6**	61.3
	≤ 6.5 %	71.4††	80.3††	85.3††	44.4
	< 5.7 %	25.8††	38.6††	48.4††	5.4
FSG (mmol/L)	Baseline (mean)	9.54	9.48	9.35	9.24
	Change from baseline	-2.68$^{\#\#}$	-3.04$^{\#\#}$	-3.29$^{\#\#}$	-3.09$^{\#\#}$
	Difference from insulin degludec [95 % CI]	0.41† [0.14, 0.69]	0.05 [-0.24, 0.33]	-0.20 [-0.48, 0.08]	-
FSG (mg/dL)	Baseline (mean)	171.8	170.7	168.4	166.4
	Change from baseline	-48.2$^{\#\#}$	-54.8$^{\#\#}$	-59.2$^{\#\#}$	-55.7$^{\#\#}$
	Difference from insulin degludec [95 % CI]	7.5† [2.4, 12.5]	0.8 [-4.3, 5.9]	-3.6 [-8.7, 1.5]	-
Body weight (kg)	Baseline (mean)	94.5	94.3	94.9	94.2
	Change from baseline	-7.5$^{\#\#}$	-10.7$^{\#\#}$	-12.9$^{\#\#}$	+2.3$^{\#\#}$
	Difference from insulin degludec [95 % CI]	-9.8** [-10.8, -8.8]	-13.0** [-14.0, -11.9]	-15.2** [-16.2, -14.2]	-
Patients (%) achieving weight loss	≥ 5 %	66.0††	83.7††	87.8††	6.3
	≥ 10 %	37.4††	55.7††	69.4††	2.9
	≥ 15 %	12.5††	28.3††	42.5††	0.0

$^{*}p < 0.05$, $^{**}p < 0.001$ for superiority, adjusted for multiplicity.
$^{\dagger}p < 0.05$, $^{\dagger\dagger}p < 0.001$ compared to insulin degludec, not adjusted for multiplicity.
$^{\#}p < 0.05$, $^{\#\#}p < 0.001$ compared to baseline, not adjusted for multiplicity.

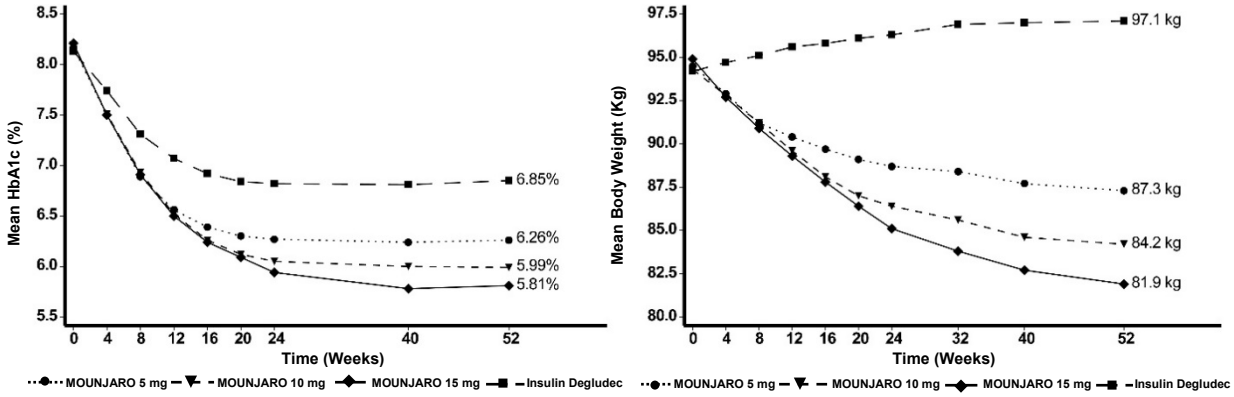

Figure 3. Mean HbA_{1c} (%) and mean body weight (kg) from baseline to week 52

SURPASS 4 – Combination therapy with 1-3 oral antidiabetic medicinal products: metformin, sulphonylureas or SGLT2i

In an active-controlled open-label study of up to 104 weeks (primary endpoint at 52 weeks), 2 002 patients with type 2 diabetes and increased cardiovascular risk were randomised to tirzepatide 5 mg, 10 mg or 15 mg once weekly or insulin glargine once daily on a background of metformin (95 %) and/or sulphonylureas (54 %) and/or SGLT2i (25 %). At baseline the patients had a mean duration of diabetes of 12 years, a mean BMI of 33 kg/m^2, a mean age of 64 years and 63 % were men. Patient treated with insulin glargine started at a dose of 10 U/day which was adjusted using an algorithm with a fasting blood glucose target of < 5.6 mmol/L. The mean dose of insulin glargine at week 52 was 44 units/day.

Table 5. SURPASS 4: Results at week 52

		Tirzepatide 5 mg	Tirzepatide 10 mg	Tirzepatide 15 mg	Titrated insulin glargine
mITT population (n)		328	326	337	998
52 weeks					
HbA_{1c} (%)	Baseline (mean)	8.52	8.60	8.52	8.51
	Change from baseline	-2.24$^{\#\#}$	-2.43$^{\#\#}$	-2.58$^{\#\#}$	-1.44$^{\#\#}$
	Difference from insulin glargine [95 % CI]	-0.80** [-0.92, -0.68]	-0.99** [-1.11, -0.87]	-1.14** [-1.26, -1.02]	-
HbA_{1c} (mmol/mol)	Baseline (mean)	69.6	70.5	69.6	69.5
	Change from baseline	-24.5$^{\#\#}$	-26.6$^{\#\#}$	-28.2$^{\#\#}$	-15.7$^{\#\#}$
	Difference from insulin glargine [95 % CI]	-8.8** [-10.1, -7.4]	-10.9** [-12.3, -9.6]	-12.5** [-13.8, -11.2]	-
Patients (%) achieving HbA_{1c}	< 7 %	81.0**	88.2**	90.7**	50.7
	≤ 6.5 %	66.0††	76.0††	81.1††	31.7
	< 5.7 %	23.0††	32.7††	43.1††	3.4
FSG (mmol/L)	Baseline (mean)	9.57	9.75	9.67	9.37
	Change from baseline	-2.80$^{\#\#}$	-3.06$^{\#\#}$	-3.29$^{\#\#}$	-2.84$^{\#\#}$
	Difference from insulin glargine [95 % CI]	0.04 [-0.22, 0.30]	-0.21 [-0.48, 0.05]	-0.44†† [-0.71, -0.18]	-
FSG (mg/dL)	Baseline (mean)	172.3	175.7	174.2	168.7
	Change from baseline	-50.4$^{\#\#}$	-54.9$^{\#\#}$	-59.3$^{\#\#}$	-51.4$^{\#\#}$
	Difference from insulin glargine [95 % CI]	1.0 [-3.7, 5.7]	-3.6 [-8.2, 1.1]	-8.0†† [-12.6, -3.4]	-
Body weight (kg)	Baseline (mean)	90.3	90.7	90.0	90.3
	Change from baseline	-7.1$^{\#\#}$	-9.5$^{\#\#}$	-11.7$^{\#\#}$	+1.9$^{\#\#}$
	Difference from insulin glargine [95 % CI]	-9.0** [-9.8, -8.3]	-11.4** [-12.1, -10.6]	-13.5** [-14.3, -12.8]	-
Patients (%) achieving weight loss	≥ 5 %	62.9††	77.6††	85.3††	8.0
	≥ 10 %	35.9††	53.0††	65.6††	1.5
	≥ 15 %	13.8††	24.0††	36.5††	0.5

* $p < 0.05$, ** $p < 0.001$ for superiority, adjusted for multiplicity.

$^{\dagger}p < 0.05$, $^{\dagger\dagger}p < 0.001$ compared to insulin glargine, not adjusted for multiplicity.

$^{\#}p < 0.05$, $^{\#\#}p < 0.001$ compared to baseline, not adjusted for multiplicity.

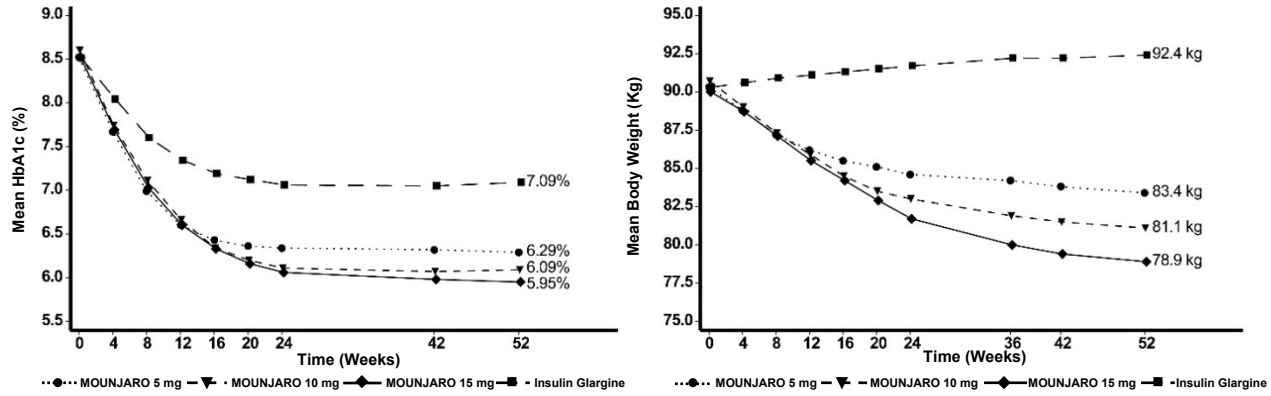

Figure 4. Mean HbA_{1c} (%) and mean body weight (kg) from baseline to week 52

SURPASS 5 - Combination therapy with titrated basal insulin, with or without metformin

In a 40 week double-blind placebo-controlled study, 475 patients with inadequate glycaemic control using insulin glargine with or without metformin were randomised to tirzepatide 5 mg, 10 mg or 15 mg once weekly or placebo. Insulin glargine doses were adjusted utilizing an algorithm with a fasting blood glucose target of < 5.6 mmol/L. At baseline the patients had a mean duration of diabetes of 13 years, a mean BMI of 33 kg/m^2, a mean age of 61 years and 56 % were men. The overall estimated median dose of insulin glargine at baseline was 34 units/day. The median dose of insulin glargine at week 40 was 38, 36, 29 and 59 units/day for tirzepatide 5 mg, 10 mg, 15 mg and placebo respectively.

Table 6. SURPASS 5: Results at week 40

		Tirzepatide 5 mg	Tirzepatide 10 mg	Tirzepatide 15 mg	Placebo
mITT population (n)		116	118	118	119
HbA_{1c} (%)	Baseline (mean)	8.29	8.34	8.22	8.39
	Change from baseline	-2.23$^{\#\#}$	-2.59$^{\#\#}$	-2.59$^{\#\#}$	-0.93$^{\#\#}$
	Difference from placebo [95 % CI]	-1.30** [-1.52, -1.07]	-1.66** [-1.88, -1.43]	-1.65** [-1.88, -1.43]	-
HbA_{1c} (mmol/mol)	Baseline (mean)	67.1	67.7	66.4	68.2
	Change from baseline	-24.4$^{\#\#}$	-28.3$^{\#\#}$	-28.3$^{\#\#}$	-10.2$^{\#\#}$
	Difference from placebo [95 % CI]	-14.2** [-16.6, -11.7]	-18.1** [-20.6, -15.7]	-18.1** [-20.5, -15.6]	-
Patients (%) achieving HbA_{1c}	< 7 %	93.0**	97.4**	94.0**	33.9
	≤ 6.5 %	80.0††	94.7††	92.3††	17.0
	< 5.7 %	26.1††	47.8††	62.4††	2.5
FSG (mmol/L)	Baseline (mean)	9.00	9.04	8.91	9.13
	Change from baseline	-3.41$^{\#\#}$	-3.77$^{\#\#}$	-3.76$^{\#\#}$	-2.16$^{\#\#}$
	Difference from placebo [95 % CI]	-1.25** [-1.64, -0.86]	-1.61** [-2.00, -1.22]	-1.60** [-1.99, -1.20]	-
FSG (mg/dL)	Baseline (mean)	162.2	162.9	160.4	164.4
	Change from baseline	-61.4$^{\#\#}$	-67.9$^{\#\#}$	-67.7$^{\#\#}$	-38.9$^{\#\#}$
	Difference from placebo [95 % CI]	-22.5** [-29.5, -15.4]	-29.0** [-36.0, -22.0]	-28.8** [-35.9, -21.6]	-
Body weight (kg)	Baseline (mean)	95.5	95.4	96.2	94.1
	Change from baseline	-6.2$^{\#\#}$	-8.2$^{\#\#}$	-10.9$^{\#\#}$	+1.7$^{\#}$
	Difference from placebo [95 % CI]	-7.8** [-9.4, -6.3]	-9.9** [-11.5, -8.3]	-12.6** [-14.2, -11.0]	-
Patients (%) achieving weight loss	≥ 5 %	53.9††	64.6††	84.6††	5.9
	≥ 10 %	22.6††	46.9††	51.3††	0.9
	≥ 15 %	7.0†	26.6†	31.6††	0.0

$^{*}p < 0.05$, ** $p < 0.001$ for superiority, adjusted for multiplicity.
$^{\dagger}p < 0.05$, $^{\dagger\dagger}p < 0.001$ compared to placebo, not adjusted for multiplicity.
$^{\#}p < 0.05$, $^{\#\#}p < 0.001$ compared to baseline, not adjusted for multiplicity.

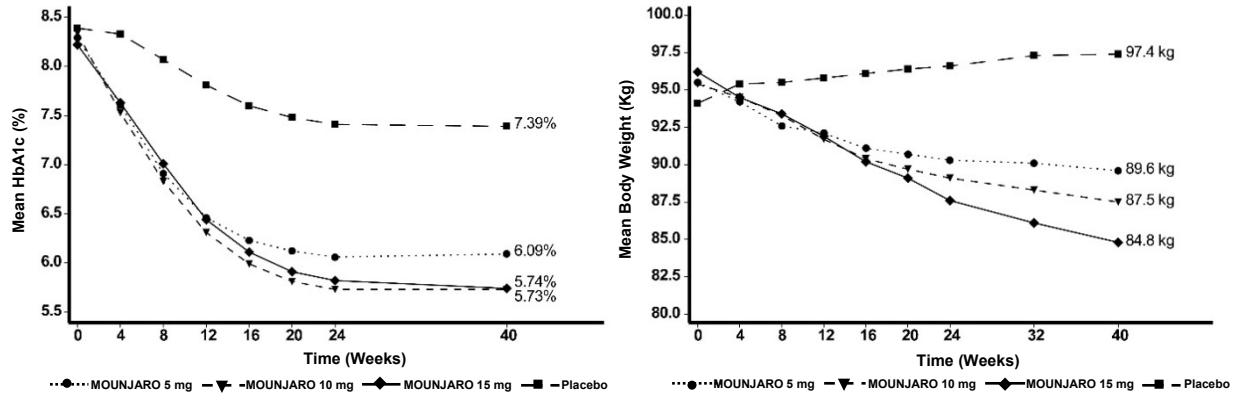

Figure 5. Mean HbA_{1c} (%) and mean body weight (kg) from baseline to week 40

Cardiovascular evaluation

Cardiovascular (CV) risk was assessed via a meta-analysis of patients with at least one adjudication confirmed major adverse cardiac event (MACE). The composite endpoint of MACE-4 included CV death, non-fatal myocardial infarction, non-fatal stroke, or hospitalisation for unstable angina.

In a primary meta-analysis of phase 2 and 3 registration studies, a total of 116 patients (tirzepatide: 60 [n = 4 410]; all comparators: 56 [n = 2 169]) experienced at least one adjudication confirmed MACE-4: The results showed that tirzepatide was not associated with excess risk for CV events compared with pooled comparators (HR: 0.81; CI: 0.52 to 1.26).

An additional analysis was conducted specifically for the SURPASS-4 study that enrolled patients with established CV disease. A total of 109 patients (tirzepatide: 47 [n = 995]; insulin glargine: 62 [n = 1 000]) experienced at least one adjudication confirmed MACE-4: The results showed that tirzepatide was not associated with excess risk for CV events compared with insulin glargine (HR: 0.74; CI: 0.51 to 1.08).

Blood pressure
In the placebo-controlled phase 3 studies, treatment with tirzepatide resulted in a mean decrease in systolic and diastolic blood pressure of 6 to 9 mmHg and 3 to 4 mmHg, respectively. There was a mean decrease in systolic and diastolic blood pressure of 2 mmHg each in placebo treated patients.

Other information

Fasting serum glucose

Treatment with tirzepatide resulted in significant reductions from baseline in FSG (changes from baseline to primary end point were -2.4 mmol/L to -3.8 mmol/L). Significant reductions from baseline in FSG could be observed as early as 2 weeks. Further improvement in FSG was seen through to 42 weeks then was sustained through the longest study duration of 104 weeks.

Postprandial glucose

Treatment with tirzepatide resulted in significant reductions in mean 2 hour post prandial glucose (mean of 3 main meals of the day) from baseline (changes from baseline to primary end point were -3.35 mmol/L to -4.85 mmol/L).

Triglycerides

Across SURPASS 1-5 trials, tirzepatide 5 mg, 10 mg and 15 mg resulted in reduction in serum triglyceride of 15-19 %, 18-27 % and 21-25 % respectively.

In the 40 week trial versus semaglutide 1 mg, tirzepatide 5 mg, 10 mg and 15 mg resulted in 19 %, 24 % and 25 % reduction in serum triglycerides levels respectively compared to 12 % reduction with semaglutide 1 mg.

Proportion of patients reaching HbA1c < 5.7 % without clinically significant hypoglycaemia

In the 4 studies where tirzepatide was not combined with basal insulin, 93.6 % to 100 % of patients who achieved a normal glycaemia of HbA1c < 5.7 % (≤ 39 mmol/mol), at the primary endpoint visit with tirzepatide treatment did so without clinically significant hypoglycaemia. In Study SURPASS-5, 85.9 % of patients treated with tirzepatide who reached HbA1c < 5.7 % (≤ 39 mmol/mol) did so without clinically significant hypoglycaemia.

Special populations

The efficacy of tirzepatide was not impacted by age, gender, race, ethnicity, region, or by baseline BMI, HbA1c, diabetes duration and level of renal function impairment.

Paediatric population

The European Medicines Agency has deferred the obligation to submit the results of studies with Mounjaro in one or more subsets of the paediatric population for the treatment of type 2 diabetes mellitus (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Tirzepatide is a 39-amino acid peptide with a C20 fatty diacid moiety that enables albumin binding and prolongs half-life.

Absorption

Maximum concentration of tirzepatide is reached 8 to 72 hours post dose. Steady state exposure is achieved following 4 weeks of once weekly administration. Tirzepatide exposure increases in a dose proportional manner.

Similar exposure was achieved with subcutaneous administration of tirzepatide in the abdomen, thigh, or upper arm.

Absolute bioavailability of subcutaneous tirzepatide was 80 %.

Distribution

The mean apparent steady-state volume of distribution of tirzepatide following subcutaneous administration in patients with type 2 diabetes is approximately 10.3 L.

Tirzepatide is highly bound to plasma albumin (99 %).

Biotransformation

Tirzepatide is metabolised by proteolytic cleavage of the peptide backbone, beta-oxidation of the C20 fatty diacid moiety and amide hydrolysis.

Elimination

The apparent population mean clearance of tirzepatide is 0.06 L/h with an elimination half-life of approximately 5 days, enabling once weekly administration.

Tirzepatide is eliminated by metabolism. The primary excretion routes of tirzepatide metabolites are via urine and faeces. Intact tirzepatide is not observed in urine or faeces.

Special populations

Age, gender, race, ethnicity, body weight

Age, gender, race, ethnicity or body weight, do not have a clinically relevant effect on the pharmacokinetics (PK) of tirzepatide.

Renal impairment

Renal impairment does not impact the PK of tirzepatide. The PK of tirzepatide after a single 5 mg dose was evaluated in patients with different degrees of renal impairment (mild, moderate, severe, ESRD) compared with subjects with normal renal function and no clinically relevant differences were observed. This was also shown for patients with both type 2 diabetes mellitus and renal impairment based on data from clinical studies.

Hepatic impairment

Hepatic impairment does not impact the PK of tirzepatide. The PK of tirzepatide after a single 5 mg dose was evaluated in patients with different degrees of hepatic impairment (mild, moderate, severe) compared with subjects with normal hepatic function and no clinically relevant differences were observed.

Paediatric population

Tirzepatide has not been studied in paediatric patients.

5.3 Preclinical safety data

Non-clinical data reveal no special hazards for humans based on conventional studies of safety pharmacology or repeat-dose toxicity or genotoxicity.

A 2-year carcinogenicity study was conducted with tirzepatide in male and female rats at doses of 0.15, 0.50, and 1.5 mg/kg (0.12, 0.36, and 1.02-fold the maximum recommended human dose (MRHD) based on AUC) administered by subcutaneous injection twice weekly. Tirzepatide caused an increase in thyroid C-cell tumours (adenomas and carcinomas) at all doses compared to controls. The human relevance of these findings is unknown.

In a 6-month carcinogenicity study in rasH2 transgenic mice, tirzepatide at doses of 1, 3, and 10 mg/kg administered by subcutaneous injection twice weekly did not produce increased incidences of thyroid C-cell hyperplasia or neoplasia at any dose.

Animal studies with tirzepatide did not indicate direct harmful effects with respect to fertility.

In animal reproduction studies, tirzepatide caused foetal growth reductions and foetal abnormalities at exposures below the MRHD based on AUC. An increased incidence of external, visceral, and skeletal malformations and visceral and skeletal developmental variations were observed in rats. Foetal growth reductions were observed in rats and rabbits. All developmental effects occurred at maternally toxic doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium phosphate dibasic heptahydrate
Sodium chloride
Concentrated hydrochloric acid, and sodium hydroxide (for pH adjustment)
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a refrigerator (2 ºC – 8 ºC).
Do not freeze.
Store in original package in order to protect from light.

Mounjaro may be stored unrefrigerated for up to 21 cumulative days at a temperature not above 30 ºC and then the pre-filled pen must be discarded.

6.5 Nature and contents of container

Glass syringe encased in a disposable pre-filled pen.

The pre-filled pen has a hidden needle, which will automatically insert into the skin when the injection button is pressed.
Each pre-filled pen contains 0.5 ml of solution.

Pack sizes of 2 pre-filled pens, 4 pre-filled pens and multipacks containing 12 (3 packs of 4) pre-filled pens. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Instructions for use

The pre-filled pen is for single-use only.

The instructions for using the pen, included with the package leaflet, must be followed carefully.
Inspect Mounjaro visually before use and discard for particulate matter or discolouration.
Mounjaro that has been frozen must not be used.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

8. MARKETING AUTHORISATION NUMBER

EU/1/22/1685/001
EU/1/22/1685/002
EU/1/22/1685/003
EU/1/22/1685/004
EU/1/22/1685/005
EU/1/22/1685/006
EU/1/22/1685/007
EU/1/22/1685/008
EU/1/22/1685/009
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EU/1/22/1685/013
EU/1/22/1685/014
EU/1/22/1685/015
EU/1/22/1685/016
EU/1/22/1685/017
EU/1/22/1685/018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Eli Lilly Italia S.p.A.
Via Gramsci 731/733
50019, Sesto Fiorentino
Firenze (FI)
Italy

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 2.5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 2.5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
2 pre-filled pens
4 pre-filled pens

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/001 2 pre-filled pens
EU/1/22/1685/002 4 pre-filled pens

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 2.5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON (with Blue Box) – multipack - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 2.5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 2.5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

Multi-pack: 12 (3 packs of 4) pre-filled pens.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly
Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/003

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 2.5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

INTERMEDIATE CARTON (without Blue Box) component of a multipack - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 2.5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 2.5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid; water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

4 pre-filled pens. Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/003

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 2.5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PRE-FILLED PEN LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Mounjaro 2.5 mg solution for injection

tirzepatide
Subcutaneous use

2. METHOD OF ADMINISTRATION

Once weekly

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 ml

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
2 pre-filled pens
4 pre-filled pens

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/004 2 pre-filled pens
EU/1/22/1685/005 4 pre-filled pens

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON (with Blue Box) – multipack - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

Multi-pack: 12 (3 packs of 4) pre-filled pens.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly
Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/006

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

INTERMEDIATE CARTON (without Blue Box) component of a multipack - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid; water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

4 pre-filled pens. Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/006

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PRE-FILLED PEN LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Mounjaro 5 mg solution for injection

tirzepatide
Subcutaneous use

2. METHOD OF ADMINISTRATION

Once weekly

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 ml

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 7.5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 7.5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
2 pre-filled pens
4 pre-filled pens

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/007 2 pre-filled pens
EU/1/22/1685/008 4 pre-filled pens

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 7.5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON (with Blue Box) – multipack - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 7.5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 7.5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

Multi-pack: 12 (3 packs of 4) pre-filled pens.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly
Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/009

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 7.5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

INTERMEDIATE CARTON (without Blue Box) component of a multipack - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 7.5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 7.5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid; water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

4 pre-filled pens. Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/009

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 7.5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PRE-FILLED PEN LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Mounjaro 7.5 mg solution for injection

tirzepatide
Subcutaneous use

2. METHOD OF ADMINISTRATION

Once weekly

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 ml

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 10 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 10 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
2 pre-filled pens
4 pre-filled pens

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/010 2 pre-filled pens
EU/1/22/1685/011 4 pre-filled pens

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 10 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON (with Blue Box) – multipack - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 10 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 10 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

Multi-pack: 12 (3 packs of 4) pre-filled pens.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly
Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/012

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 10 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

INTERMEDIATE CARTON (without Blue Box) component of a multipack - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 10 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 10 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid; water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

4 pre-filled pens. Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/012

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 10 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PRE-FILLED PEN LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Mounjaro 10 mg solution for injection

tirzepatide
Subcutaneous use

2. METHOD OF ADMINISTRATION

Once weekly

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 ml

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 12.5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 12.5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
2 pre-filled pens
4 pre-filled pens

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/013 2 pre-filled pens
EU/1/22/1685/014 4 pre-filled pens

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 12.5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON (with Blue Box) – multipack - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 12.5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 12.5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

Multi-pack: 12 (3 packs of 4) pre-filled pens.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly
Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/015

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 12.5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

INTERMEDIATE CARTON (without Blue Box) component of a multipack – PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 12.5 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 12.5 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid; water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

4 pre-filled pens. Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/015

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 12.5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PRE-FILLED PEN LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Mounjaro 12.5 mg solution for injection

tirzepatide
Subcutaneous use

2. METHOD OF ADMINISTRATION

Once weekly

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 ml

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 15 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 15 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection
2 pre-filled pens
4 pre-filled pens

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/016 2 pre-filled pens
EU/1/22/1685/017 4 pre-filled pens

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 15 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON (with Blue Box) – multipack - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 15 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 15 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid, water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

Multi-pack: 12 (3 packs of 4) pre-filled pens.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly
Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/018

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 15 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

INTERMEDIATE CARTON (without Blue Box) component of a multipack - PRE-FILLED PEN

1. NAME OF THE MEDICINAL PRODUCT

Mounjaro 15 mg solution for injection in pre-filled pen

tirzepatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each pre-filled pen contains 15 mg of tirzepatide in 0.5 ml solution

3. LIST OF EXCIPIENTS

Excipients: Sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide, concentrated hydrochloric acid; water for injections. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

4 pre-filled pens. Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For single use only
Once weekly

Mark the day of the week you want to use your medicine to help you remember.

	Mon.	Tue.	Wed.	Thu.	Fri.	Sat.	Sun.
Week 1							
Week 2							
Week 3							
Week 4							

Read the package leaflet before use.
Subcutaneous use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Can be stored unrefrigerated not above 30 ºC for up to 21 days.
Do not freeze.
Store in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly Nederland B.V.
Papendorpseweg 83, 3528 BJ Utrecht
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/22/1685/018

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MOUNJARO 15 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PRE-FILLED PEN LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Mounjaro 15 mg solution for injection

tirzepatide
Subcutaneous use

2. METHOD OF ADMINISTRATION

Once weekly

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 ml

6. OTHER

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Mounjaro 2.5 mg solution for injection in pre-filled pen
Mounjaro 5 mg solution for injection in pre-filled pen
Mounjaro 7.5 mg solution for injection in pre-filled pen
Mounjaro 10 mg solution for injection in pre-filled pen
Mounjaro 12.5 mg solution for injection in pre-filled pen
Mounjaro 15 mg solution for injection in pre-filled pen
tirzepatide

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mounjaro is and what it is used for

Mounjaro contains an active substance called tirzepatide and is used to treat adults with type 2 diabetes mellitus. Mounjaro reduces the level of sugar in the body only when the levels of sugar are high.

Mounjaro is used:
- on its own when you can’t take metformin (another diabetes medicine).
- with other medicines for diabetes when they are not enough to control your blood sugar levels. These other medicines may be medicines taken by mouth and/or insulin given by injection.

It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.

2. What you need to know before you use Mounjaro

Do not use Mounjaro
- if you are allergic to tirzepatide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Mounjaro if:

- you have severe problems with food digestion or food remaining in your stomach for longer than normal (including severe gastroparesis).
- you have ever had pancreatitis (inflammation of the pancreas which may cause severe pain in the stomach and back which does not go away).
- you have a problem with your eyes (diabetic retinopathy or macular oedema).
- you are using a sulphonylurea (another diabetes medicine) or insulin for your diabetes, as low blood sugar (hypoglycaemia) can occur. Your doctor may need to change your dose of these other medicines to reduce this risk.

When starting treatment with Mounjaro, in some cases you may experience loss of fluids/dehydration, e.g. due to vomiting, nausea and/or diarrhoea, which may lead to a decrease in kidney function. It is important to avoid dehydration by drinking plenty of fluids. Contact your doctor if you have any questions or concerns.

Children and adolescents
This medicine should not be given to children and adolescents under 18 years of age because it has not been studied in this age group.

Other medicines and Mounjaro
Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This medicine should not be used during pregnancy as the effects of this medicine on an unborn child are not known. Therefore, it is recommended to use contraception while using this medicine.

Breast-feeding
It is unknown whether tirzepatide passes into breast milk. A risk to newborns/infants cannot be ruled out. If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you should stop breast-feeding or delay using Mounjaro.

Driving and using machines
It is unlikely that this medicine will affect your ability to drive and use machines. However, if you use Mounjaro in combination with a sulphonylurea or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar, e.g. headache, drowsiness, weakness, dizziness, feeling hungry, confusion, irritability, fast heartbeat and sweating (see section 4). See section 2, 'Warnings and precautions' for information on increased risk of low blood sugar. Talk to your doctor for further information.

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

3. How to use Mounjaro

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure how to use this medicine.

How much to use
- The starting dose is 2.5 mg once a week for four weeks. After four weeks your doctor will increase your dose to 5 mg once a week.

- Your doctor may increase your dose by 2.5 mg increments to 7.5 mg, 10 mg, 12.5 mg or 15 mg once a week if you need it. In each case your doctor will tell you to stay on a particular dose for at least 4 weeks before going to a higher dose.

Do not change your dose unless your doctor has told you to.

Choosing when to give Mounjaro
Each pen contains one dose of Mounjaro either 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg.

You can use your pen at any time of the day, with or without meals. You should use it on the same day each week if you can. To help you remember, when to use Mounjaro, you may wish to tick the day of the week when you inject your first dose on the box that your pen comes in, or mark it on a calendar.

If necessary, you can change the day of your weekly Mounjaro injection, as long as it has been at least 3 days since your last injection. After selecting a new dosing day, continue with once-a-week dosing on that new day.

How to inject Mounjaro
Mounjaro is injected under the skin (subcutaneous injection) of your stomach area (abdomen) or upper leg (thigh) or upper arm. You may need help from someone else if you want to inject in your upper arm.

If you want to do so, you can use the same area of your body each week. But be sure to choose a different injection site within that area. If you also inject insulin choose a different injection site for that injection.

Testing blood glucose levels
If you are using Mounjaro with a sulphonylurea or insulin, it is important that you test your blood glucose levels as instructed by your doctor, pharmacist or nurse (see section 2, 'Warnings and precautions').

Read the "Instructions for Use" for the pen carefully before using Mounjaro.

If you use more Mounjaro than you should
If you use more Mounjaro than you should talk to your doctor immediately. Too much of this medicine may cause low blood sugar (hypoglycaemia) and can make you feel sick or be sick.

If you forget to use Mounjaro
If you forget to inject a dose and,
- it has been **4 days or less** since you should have used Mounjaro, use it as soon as you remember. Then inject your next dose as usual on your scheduled day.
- If it has been **more than 4 days** since you should have used Mounjaro, skip the missed dose. Then inject your next dose as usual on your scheduled day.

Do not use a double dose to make up for a forgotten dose. The minimum time between two doses must be at least 3 days.

If you stop using Mounjaro
Do not stop using Mounjaro without talking with your doctor. If you stop using Mounjaro, your blood sugar levels can increase.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Uncommon (may affect up to 1 in 100 people)
- Inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away. You should see a doctor immediately if you experience such symptoms.

Other side effects

Very common **(**may affect more than 1 in 10 people)
- Feeling sick (nausea)
- Diarrhoea

These side effects are usually not severe. They are most common when first starting tirzepatide but decrease over time in most patients.

- Low blood sugar (hypoglycaemia) is very common when tirzepatide is used with medicines that contain a sulphonylurea and/or insulin. If you are using a sulphonylurea or insulin, the dose may need to be lowered while you use tirzepatide (see section 2, 'Warnings and precautions'). Symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, feeling hungry, confusion, irritability, fast heartbeat and sweating. Your doctor should tell you how to treat low blood sugar.

Common **(**may affect up to 1 in 10 people)
- Low blood sugar (hypoglycaemia) is common when tirzepatide is used with both metformin and a sodium-glucose co-transporter 2 inhibitor (another diabetes medicine)
- Allergic reaction (hypersensitivity) (e.g., rash, itching, and eczema)
- Feeling less hungry (decreased appetite)
- Stomach (abdominal) pain
- Being sick (vomiting) – this usually goes away over time
- Indigestion (dyspepsia)
- Constipation
- Bloating of the stomach
- Burping (eructation)
- Gas (flatulence)
- Reflux or heartburn (also called gastroesophageal reflux disease – GERD) - a disease caused by stomach acid coming up into the tube from your stomach to your mouth
- Feeling tired (fatigue)
- Injection site reactions (e.g. itching or redness)
- Fast pulse
- Increased levels of pancreatic enzymes (such as lipase and amylase) in blood.

Uncommon **(**may affect up to 1 in 100 people)
- Low blood sugar (hypoglycaemia) is uncommon when tirzepatide is used with metformin.
- Gallstones
- Weight loss
- Increased calcitonin levels in blood.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Mounjaro

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pen label and on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze. If the pen has been frozen, DO NOT USE

Store in the original packaging in order to protect from light.

Mounjaro can be stored unrefrigerated not above 30 ºC for up to 21 cumulative days and then the pen must be discarded.

Do not use this medicine if you notice that the pen is damaged, or the medicine is cloudy, discoloured or has particles in it.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mounjaro contains
The active substance is tirzepatide.
- *Mounjaro 2.5 mg:* Each pre-filled pen contains 2.5 mg of tirzepatide in 0.5 ml solution.
- *Mounjaro 5 mg:* Each pre-filled pen contains 5 mg of tirzepatide in 0.5 ml solution.
- *Mounjaro 7.5 mg:* Each pre-filled pen contains 7.5 mg of tirzepatide in 0.5 ml solution.
- *Mounjaro 10 mg:* Each pre-filled pen contains 10 mg of tirzepatide in 0.5 ml solution.
- *Mounjaro 12.5 mg:* Each pre-filled pen contains 12.5 mg of tirzepatide in 0.5 ml solution.
- *Mounjaro 15 mg:* Each pre-filled pen contains 15 mg of tirzepatide in 0.5 ml solution.

The other ingredients are sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide (see section 2 under ‘Mounjaro contains sodium’ for further information); concentrated hydrochloric acid and water for injections.

What Mounjaro looks like and contents of the pack
Mounjaro is a clear, colourless to slightly yellow, solution for injection in a pre-filled pen.
The pre-filled pen has a hidden needle which will automatically insert into the skin when the injection button is pressed. The pre-filled pen will retract the needle when the injection is completed.
Each pre-filled pen contains 0.5 ml solution.
The pre-filled pen is for single use only.
Pack sizes of 2 pre-filled pens, 4 pre-filled pens or multipacks of 12 (3 packs of 4) pre-filled pens. Not all pack sizes may be available in your country.

Marketing Authorisation Holder
Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

Manufacturer
Eli Lilly Italia S.p.A.,Via Gramsci 731/733, 50019, Sesto Fiorentino, Firenze (FI), Italy

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This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

Instructions for use

Mounjaro 2.5 mg solution for injection in pre-filled pen
Mounjaro 5 mg solution for injection in pre-filled pen
Mounjaro 7.5 mg solution for injection in pre-filled pen
Mounjaro 10 mg solution for injection in pre-filled pen
Mounjaro 12.5 mg solution for injection in pre-filled pen
Mounjaro 15 mg solution for injection in pre-filled pen
tirzepatide

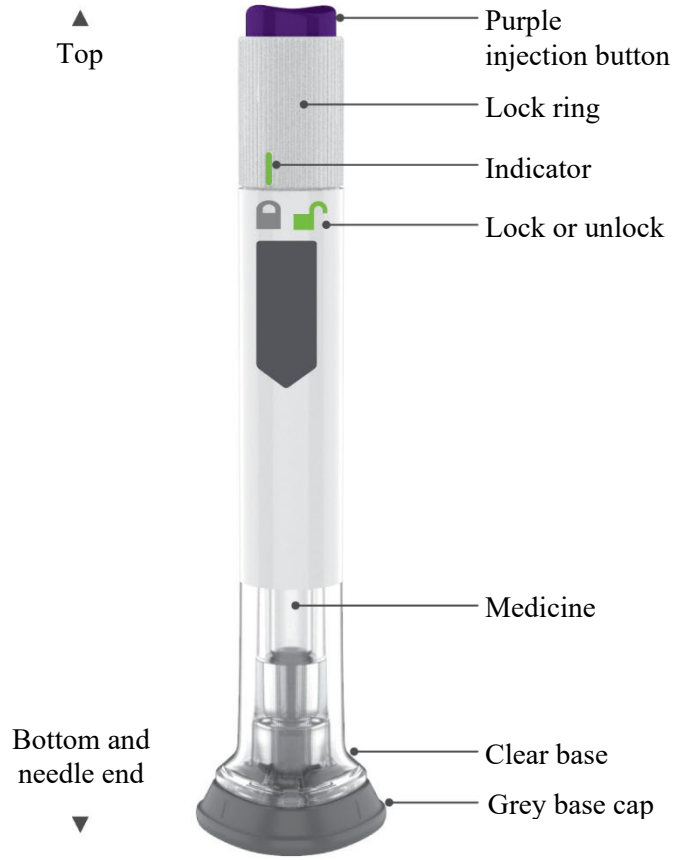
Important information you need to know before injecting Mounjaro.

Read this instructions for use and the package leaflet before using your Mounjaro pre-filled pen (pen) and each time you get a new pen. There may be new information. This information does not take the place of talking to your doctor, pharmacist or nurse about your medical condition or treatment.

Talk to your doctor, pharmacist or nurse about how to inject Mounjaro the right way.
- Mounjaro is a single-dose pre-filled pen.
- The pen has a hidden needle which will automatically insert into your skin when the injection button is pressed. The pen will retract the needle when the injection is completed.
- Mounjaro is used 1 time each week.
- Inject under the skin (subcutaneously) only.
- You or another person can inject into your stomach (abdomen), upper leg (thigh) or upper arm.
- You may need help from someone else if you want to inject in your upper arm.

Storage and handling
- For storage instructions refer to section 5 of the patient information leaflet.
- The pen has glass parts. Handle it carefully. If you drop the pen on a hard surface, **do not** use it. Use a new pen for your injection.

Guide to parts

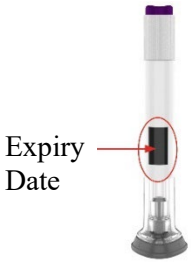


Preparing to inject Mounjaro

Remove the pen from the refrigerator.

Leave the grey base cap on until you are ready to inject.

Check the pen label to make sure you have the right medicine and dose, and that it has not expired.



Inspect the pen to make sure that it is not damaged.

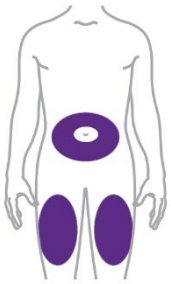
Make sure the medicine is:

- not frozen
- clear and not discoloured
- not cloudy
- does not have particles

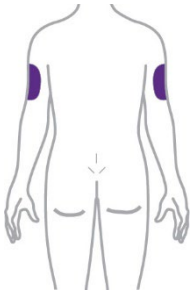
Wash your hands.

Choose your injection site

Your doctor, pharmacist or nurse can help you choose the injection site that is best for you.



You or another person can inject the medicine in your stomach (abdomen) or thigh.



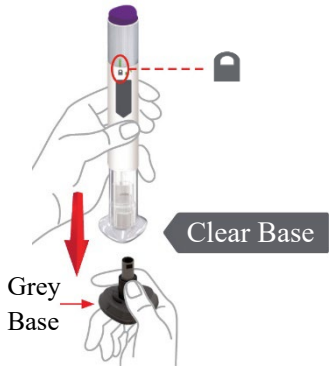
Another person should give you the injection in the back of your upper arm.

Change (rotate) your injection site each week.

You may use the same area of your body, but be sure to choose a different injection site in that area.

Step **1** **Pull off the grey base cap**

Make sure the pen is **locked**.



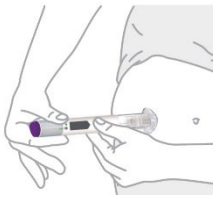
Do not unlock the pen until you place the clear base on your skin and are ready to inject.

Pull the grey base cap straight off and throw it away.

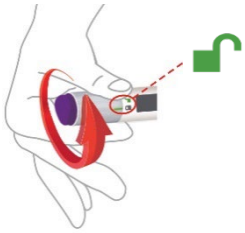
Do not put the grey base cap back on – this could damage the needle.

Do not touch the needle.

Step **2** **Place clear base on skin, then unlock**

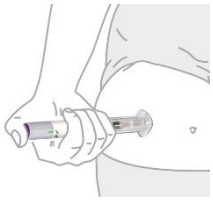


Place the clear base flat against your skin at the injection site.



Unlock by turning the lock ring.

Step **3** **Press and hold up to 10 seconds**



Press and hold the purple injection button.

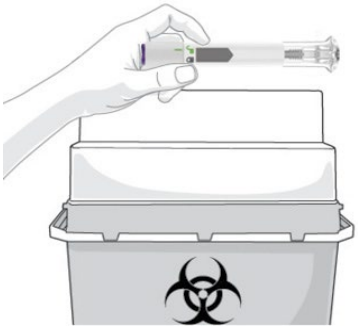
Listen for:
- First click = injection started
- Second click = injection completed

You will know your injection is complete when the grey plunger is visible.

After your injection, place the used pen in a sharps container.

Disposal of your used pen

- Throw away (dispose of) the pen in a sharps container or as directed by your doctor, pharmacist or nurse. **Do not** throw away (dispose of) pens in your household waste.
- Do not recycle your used sharps disposal container.
- Ask your doctor, pharmacist or nurse about how to dispose of medicines you no longer use.



Commonly asked questions

What if I see air bubbles in my pen?
Air bubbles are normal.

What if my pen is not at room temperature?
It is not necessary to warm the pen to room temperature.

What if I unlock the pen and press the purple injection button before pulling off the grey base cap?
Do not remove the grey base cap. Throw away the pen and get a new pen.

What if there is a drop of liquid on the tip of the needle when I remove the grey base cap?
A drop of liquid on the tip of the needle is normal. **Do not** touch the needle.

Do I need to hold the injection button down until the injection is complete?
This is not necessary, but it may help you keep the pen steady against your skin.

I heard more than 2 clicks during my injection — 2 loud clicks and 1 soft one. Did I get my complete injection?
Some people may hear a soft click right before the second loud click. That is the normal operation of the pen. **Do not** remove the pen from your skin until you hear the second loud click.

I am not sure if my pen worked the right way.

Check to see if you have received your dose. Your dose was delivered the right way if the grey plunger is visible. Also, see **Step 3** of the instructions.

If you do not see the grey plunger, contact Lilly for further instructions. Until then, store your pen safely to avoid an accidental needle injury.

What if there is a drop of liquid or blood on my skin after my injection?
This is normal. Press a cotton ball or gauze over the injection site. **Do not** rub the injection site.

Other information
- If you have vision problems, **do not** use your pen without help from a person trained to use the Mounjaro pen.

Where to learn more
- If you have questions or problems with your Mounjaro pen, contact Lilly or your doctor, pharmacist or nurse.

Last revised in