

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ONSWIK safely and effectively. See full prescribing information for ONSWIK.

ONSWIK (insulin efsitora alfa-gobe) injection, for subcutaneous use

Initial U.S. Approval: 2026

INDICATIONS AND USAGE

ONSWIK™ is a long-acting insulin analog indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. (1)

Limitations of Use:

- Not recommended for use in patients with type 1 diabetes mellitus due to increased risk of severe hypoglycemia (1)

DOSAGE AND ADMINISTRATION

- See Full Prescribing Information for general dosing and important administration instructions. (2.1, 2.2)
- Administer once weekly on the same day each week. The scheduled injection day may be changed, provided 4 days have elapsed since the last dose. Once the injection day is changed, continue administering ONSWIK on the new chosen day. (2.1)
- Individualize and adjust the dosage based on metabolic needs, glucose monitoring results and glycemic control goal. (2.1)
- Inject subcutaneously into the abdomen, upper arm, thigh, or buttocks. (2.2)
- Rotate injection sites to reduce risk of lipodystrophy and localized cutaneous amyloidosis. (2.2)
- May administer alone or in any combination with oral and injectable antidiabetic medicines and bolus insulin. (2.2)
- See Full Prescribing Information for recommended starting dosage in insulin naïve patients and patients already on a daily basal insulin. (2.3, 2.4)

DOSAGE FORMS AND STRENGTHS

Injection: clear and colorless to yellow solution available as:

- 500 units/mL (U-500): 3 mL single-patient-use KwikPen (containing 1,500 units) (3)
- 1,000 units/mL (U-1,000): 3 mL single-patient-use KwikPen (containing 3,000 units) (3)

CONTRAINDICATIONS

- During episodes of hypoglycemia (4)
- Hypersensitivity to insulin efsitora alfa-gobe or any of the excipients in ONSWIK (4)

WARNINGS AND PRECAUTIONS

- Hypoglycemia Due to Medication Errors and Accidental Overdose:** Accidental mix-ups between insulin products can occur. Advise

patients to always check the product label before each injection to confirm they are using ONSWIK and not another insulin or injectable antidiabetic medicine. Do not transfer ONSWIK into a syringe as overdosage and severe hypoglycemia can result. Do not repeat the one-time starting dose after the first injection. (5.1)

- Hypoglycemia:** May be life-threatening. Increase frequency of glucose monitoring with changes to insulin dosage, co-administered glucose-lowering medications, meal pattern, physical activity, and in patients with renal impairment or hepatic impairment or hypoglycemia unawareness. (5.3)
- Hyperglycemia or Hypoglycemia with changes in insulin regimen:** Make changes to a patient's insulin regimen (e.g., insulin strength, manufacturer, type, injection site or method of administration) under close medical supervision with increased frequency of glucose monitoring. (5.4)
- Hypersensitivity Reactions:** Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue ONSWIK, monitor and treat if indicated. (5.5)
- Hypokalemia:** May be life-threatening. Monitor potassium levels in patients at risk for hypokalemia and treat if indicated. (5.6)
- Never share ONSWIK** between patients, even if the needle is changed. (5.7)
- Fluid Retention and Heart Failure with Concomitant Use of PPAR-Gamma Agonists:** Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation of the PPAR-gamma agonist if heart failure occurs. (5.8)

ADVERSE REACTIONS

Common adverse reactions include hypoglycemia, hypersensitivity reactions, injection site reactions, lipodystrophy, pruritus, rash, edema, and weight gain. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Drugs that Increase Hypoglycemia Risk or Increase or Decrease Glucose-Lowering Effect:** Adjustment of the ONSWIK dosage may be needed; closely monitor glucose. (7)
- Drugs that Blunt Hypoglycemia Signs and Symptoms (e.g., beta-blockers, clonidine, guanethidine, and reserpine):** Increased frequency of glucose monitoring may be required. (7)

USE IN SPECIFIC POPULATIONS

- Pregnancy:** Use during pregnancy is not recommended. (8.1)
- Lactation:** Use during breastfeeding or lactation is not recommended. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ONSWIK™ is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

ONSWIK is not recommended for use in patients with type 1 diabetes mellitus due to increased risk of severe hypoglycemia. [see *Warnings and Precautions* (5.2)].

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Instructions

- ONSWIK is available as a single-patient-use prefilled pen (KwikPen) in 2 concentrations (U-500 and U-1,000).
 - The U-500 KwikPen delivers doses in 5-unit increments and can deliver up to 400 units in a single injection.
 - The U-1,000 KwikPen delivers doses in 10-unit increments and can deliver up to 800 units in a single injection.
- Administer ONSWIK by subcutaneous injection once weekly on the same day each week. If necessary, the scheduled injection day may be changed, provided at least 4 days have elapsed since the last dose. Once the injection day is changed, continue administering ONSWIK on the new chosen day.
- Do not repeat administration of the one-time starting dose [see *Dosage and Administration* (2.6), *Warnings and Precautions* (5.1)].
- Individualize and adjust the dosage of ONSWIK based on metabolic needs, glucose monitoring results and glycemic control goal. If glycemic control does not improve despite adherence to diet, medication adherence, and escalating dosages of ONSWIK, consider switching to another insulin product [see *Immunogenicity* (12.6)].
- The potency of insulin analogs, including ONSWIK, is expressed in units. One (1) unit of ONSWIK corresponds to 1 international unit of human insulin.
- Consider the long half-life of ONSWIK when adjusting the dosage. When the dosage is adjusted, initial changes in fasting blood glucose (FBG) are expected within 1 to 2 weeks, with the full treatment effect of the dosage adjustment occurring in approximately 4 weeks [see *Clinical Pharmacology* (12.2, 12.3)].
- Dosage adjustment is not recommended during acute illness nor when patients make short-term changes in their physical activity level or usual diet. In these situations, consider other applicable adjustments, e.g., glucose intake or changes to other glucose lowering medication [see *Clinical Pharmacology* (12.2, 12.3)].

2.2 Important Administration Instructions

- Always check insulin labels before administration [see *Warnings and Precautions* (5.1)].
- Inspect ONSWIK visually before use. Only use ONSWIK if the solution is clear and colorless to yellow with no visible particles.
- Prior to initiation, train patients and their caregiver(s) on how to select their weekly ONSWIK dosage.
- Instruct patients to visually verify the dialed units on the dose window of the ONSWIK KwikPen before each injection to avoid dosing errors, including underdosage and overdosage, that may lead to hyperglycemia or hypoglycemia, respectively.
- Inject ONSWIK subcutaneously into the abdomen, upper arm, thigh, or buttocks.
- Rotate injection sites within the same region from one injection to the next to reduce the risk of lipodystrophy and localized cutaneous amyloidosis. Do not inject into areas of lipodystrophy or localized cutaneous amyloidosis [see *Warnings and Precautions* (5.4), *Adverse Reactions* (6.1)].
- During changes to a patient's insulin regimen, increase the frequency of glucose monitoring [see *Warnings and Precautions* (5.4)].
- Use ONSWIK prefilled pen products with caution in patients with visual impairment who may rely on audible clicks to dial their dose.
- ONSWIK may be administered alone or in any combination with oral and injectable antidiabetic medicines and rapid-acting or short-acting insulin products.
- Do not administer ONSWIK intramuscularly, intravenously or in an insulin pump.
- Do not dilute or mix ONSWIK with any insulin product or other solutions.
- Do not transfer ONSWIK from the prefilled pen to a syringe for administration [see *Warnings and Precautions* (5.1)].

2.3 Recommended Dosage in Insulin Naïve Patients

There are two dosing options for insulin naïve patients: a fixed-dosage titration and a flexible-dosage titration.

Fixed-Dosage Titration

- The recommended starting dosage is 100 units injected subcutaneously once weekly on the same day each week.
- After a minimum of 4 weeks, titrate the dosage based on the patient's metabolic needs, glucose monitoring results and glycemic goal according to Table 1.

Table 1: Fixed-Dosage Titration

Dosing	Dosage (units) once weekly
Recommended starting dosage	100
• After a minimum of 4 weeks on a stable dose, if the fasting glycemic goal has not been reached and the FBG is above 130 mg/dL, titrate sequentially to the next higher dose shown on the right. • If the patient experiences hypoglycemia within the prior week, withhold further dosage increases until the cause has been addressed and hypoglycemia has resolved.	150
	250
	400
If the FBG is below 130 mg/dL and the fasting glycemic goal has not been reached, titrate the dosage by 20 to 40 units per week as necessary. If a dosage greater than 400 units once weekly is required to reach glycemic goal, titrate the dosage by 20 to 40 units per week as necessary.	

Flexible-Dosage Titration

See Table 2 for dosage and important considerations for the flexible-dosage titration.

Table 2: Flexible-Dosage Titration

Week	Dosage (units)	Important Considerations
First week	300	The 300-unit One-Time Starting Dose is only administered during the first week.
Second week	100	Do not repeat the 300-unit One-Time Starting Dose.
Third and subsequent weeks	Adjust the ONSWIK dosage by 20 units to 40 units per week.	Titrate the dosage as necessary based on the patient's fasting glycemic goal.

2.4 Switching from Once- or Twice-Daily Basal Insulin to ONSWIK

- Administer the first dose of ONSWIK on the day after the last dose of once- or twice-daily basal insulin.
- Close glucose monitoring is recommended during the switch and until the dosage and glycemic control are stable.
- Doses and timing of concurrent mealtime insulin products or other concomitant antidiabetic medications may require adjustments.
- See Table 3 for dosage calculations and important considerations when switching patients from once- or twice-daily basal insulin to ONSWIK.

Table 3: Switching From Once- or Twice-Daily Basal Insulin to ONSWIK

Weekly Dosage	Dosage Calculation (units) ^a	Important Considerations
First week	<u>One-Time Starting Dose:</u> Multiply the total daily basal ^b insulin dosage by 7, then multiply by 3.	The One-Time Starting Dose is only administered during the first week.

	<u>For patients who have FBG values less than or equal to 120 mg/dL on daily basal insulin:</u> Consider omitting the One-Time Starting Dose. Instead, the first week dose is the total daily basal^b insulin dosage multiplied by 7	<u>If the One-Time Starting Dose is omitted:</u> Transient hyperglycemia may occur and last 4 to 6 weeks.
Second week	Multiply the previous total daily basal^b insulin dosage by 7	Do not repeat the One-Time Starting Dose.
Third and subsequent weeks	Adjust the ONSWIK dosage by 20 units to 40 units per week, as necessary based on the fasting glycemic goal.	<u>If the One-Time Starting Dose was omitted:</u> - Do not adjust the weekly dosage of ONSWIK until FBG levels have stabilized. - If the FBG level is stable and remains above the goal, the dosage may be adjusted, as necessary based on the patient's fasting glycemic goal.

^a Round calculated doses to the nearest 5 units for the U-500 KwikPen and 10 units for the U-1,000 KwikPen.

^b For patients switching from once-daily insulin glargine 300 units/mL or twice-daily NPH insulin to ONSWIK, use 80% of the total daily insulin glargine or NPH insulin dosage when calculating ONSWIK dosages.

2.5 Recommendations Regarding Missed Dose

- If a dose is missed:
 - Administer the missed dose as soon as possible within 4 days of the missed dose then maintain the regular weekly dosing schedule.
 - If more than 4 days have passed there are two options. Patients can skip the missed dose and administer the usual dose on the regularly scheduled day. Alternatively, patients can administer the missed dose then resume the once-weekly dosing schedule, one week from the day the missed dose was administered.
- Increase blood glucose monitoring with missed dosage.

2.6 Management of Accidental Extra Dose(s)

- If the one-time starting dose is accidentally administered more than once (for example, if the one-time starting dose is administered for 2 consecutive weeks), skip the next week's dose.
- If the weekly dosage is administered more than once in the same week, skip the next week's dose.
- Monitor glucose levels more frequently and assess for repeated or severe hypoglycemia.

3 DOSAGE FORMS AND STRENGTHS

Injection: clear and colorless to yellow solution available as:

- 500 units/mL (U-500): 3 mL single-patient-use KwikPen (containing 1,500 units)
- 1,000 units/mL (U-1,000): 3 mL single-patient-use KwikPen (containing 3,000 units)

4 CONTRAINDICATIONS

ONSWIK is contraindicated:

- during episodes of hypoglycemia [see *Warnings and Precautions* (5.3)].
- in patients with hypersensitivity to insulin efsitora alfa-gobe or any of the excipients in ONSWIK. Serious hypersensitivity reactions, including anaphylaxis, have occurred with insulin and insulin analogs [see *Warnings and Precautions* (5.5)].

5 WARNINGS AND PRECAUTIONS

5.1 Hypoglycemia Due to Medication Errors and Accidental Overdose

Serious hypoglycemia requiring hospitalization has occurred due to accidental mix-ups between once-weekly insulin products and other insulin products or once-weekly injectable antidiabetic medicines, incorrect dose selection, and dosing frequency errors.

To avoid dosing errors when switching from daily basal insulin to ONSWIK, follow the dosage recommendations in the Dosage and Administration Section (2.4). Administer ONSWIK once weekly only. Do not repeat administration of the one-time starting dose.

Advise patients to always check the product label before each injection to confirm they are using ONSWIK and not another insulin or injectable antidiabetic medicine. Prior to initiation, train patients and their caregiver(s) on how to select their weekly ONSWIK dosage. Advise patients using other injectable medications for glycemic control that the dosage selection of ONSWIK differs. Instruct patients to visually verify the dialed units on the dose window of the ONSWIK KwikPen before each injection to avoid dosing errors. Patients should not dial the maximum single dose (400 units for the U-500 KwikPen or 800 units for the U-1,000 KwikPen) of ONSWIK unless this is the prescribed dose. Patients should not use a syringe to remove ONSWIK from the ONSWIK KwikPen. The markings on the syringe will not measure the dose correctly and this can result in overdosage and severe hypoglycemia [see *Dosage and Administration* (2.2, 2.3, 2.4), *Instructions for Use*].

Monitor patients for signs and symptoms of hypoglycemia, particularly during the first several weeks after initiation or dose escalation of ONSWIK. Ensure patients understand how to recognize and manage hypoglycemia [see *Warnings and Precautions* (5.3)].

5.2 Severe Hypoglycemia in Patients with Type 1 Diabetes Mellitus

ONSWIK is not recommended for use in patients with type 1 diabetes mellitus due to increased risk of severe hypoglycemia. In a 52-week clinical trial of adults with type 1 diabetes mellitus, the incidence of Level 3 (severe) hypoglycemia was higher for patients treated with ONSWIK compared with insulin degludec (10% versus 3%).

5.3 Hypoglycemia

Hypoglycemia is the most common adverse reaction associated with insulins, including ONSWIK [see *Adverse Reactions* (6.1)]. Severe hypoglycemia can cause seizures, may lead to unconsciousness, may be life-threatening, or cause death. Hypoglycemia can impair concentration ability and reaction time; this may place an individual and others at risk in situations where these abilities are important (e.g., driving or operating other machinery).

Hypoglycemia can happen suddenly, and symptoms may differ in each individual and change over time in the same individual. Symptomatic awareness of hypoglycemia may be less pronounced in patients with longstanding diabetes, in patients with diabetic nerve disease, in patients using medications that block the sympathetic nervous system (e.g., beta-blockers) [see *Drug Interactions* (7)], or in patients who experience recurrent hypoglycemia.

The long-acting effect of ONSWIK may delay recovery from hypoglycemia compared to shorter-acting insulins [see *Clinical Pharmacology* (12.2, 12.3)].

Risk Factors for Hypoglycemia

The risk of hypoglycemia generally increases with intensity of glycemic control. The risk of hypoglycemia after an injection is related to the duration of action of the insulin [see *Clinical Pharmacology* (12.2)] and, in general, is highest when the glucose lowering effect of the insulin is maximal. As with all insulins, the glucose lowering effect over time of ONSWIK may vary among different individuals or at different times in the same individual and depends on many conditions, including the area of injection as well as the injection site blood supply and temperature.

Other factors that may increase the risk of hypoglycemia include changes in meal pattern (e.g., macronutrient content or timing of meals), changes in level of physical activity, or changes to co-administered medication [see *Drug Interactions* (7)]. Patients with renal or hepatic impairment may be at higher risk of hypoglycemia [see *Use in Specific Populations* (8.6, 8.7)].

Risk Mitigation Strategies for Hypoglycemia

Educate patients and caregivers to recognize and manage hypoglycemia. Self-monitoring of blood glucose plays an essential role in the prevention and management of hypoglycemia. In patients at higher risk for hypoglycemia and patients who have reduced symptomatic awareness of hypoglycemia, increased frequency of blood glucose monitoring is recommended.

5.4 Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen

Changes in an insulin regimen (e.g., insulin strength, manufacturer, type, injection site or method of administration) may affect glycemic control and predispose to hypoglycemia [see *Warnings and Precautions* (5.3)] or hyperglycemia. Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis have been reported to result in hyperglycemia; and a sudden change in the injection site (to an unaffected area) has been reported to result in hypoglycemia [see *Adverse Reactions* (6.1)].

The risk of hyperglycemia may be increased during the first four to six weeks of titration, especially if ONSWIK is initiated without the one-time starting dose [see *Dosage and Administration* (2.3, 2.4), *Clinical Pharmacology* (12.2, 12.3)].

Make any changes to a patient's insulin regimen under close medical supervision with increased frequency of glucose monitoring. Advise patients who have repeatedly injected into areas of lipodystrophy or localized cutaneous amyloidosis to change the injection site to unaffected areas and closely monitor for hypoglycemia. Adjustments in concomitant anti-diabetic treatment may be needed [see *Dosage and Administration* (2.3, 2.4)].

5.5 Hypersensitivity Reactions

Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulins, including ONSWIK [see *Adverse Reactions* (6.1)]. If hypersensitivity reactions occur, discontinue ONSWIK; treat per standard of care and monitor until symptoms and signs resolve. ONSWIK is contraindicated in patients who have had hypersensitivity reactions to insulin efsitora alfa-gobe or any of the excipients in ONSWIK [see *Contraindications* (4)].

5.6 Hypokalemia

All insulins, including ONSWIK, cause a shift in potassium from the extracellular to intracellular space, possibly leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia (e.g., patients using potassium-lowering medications, patients taking medications sensitive to serum potassium concentrations) and treat if indicated.

5.7 Never Share an ONSWIK Prefilled Pen Between Patients

ONSWIK prefilled pens must never be shared between patients, even if the needle is changed. Sharing poses a risk for transmission of blood-borne pathogens.

5.8 Fluid Retention and Heart Failure with Concomitant Use of PPAR-Gamma Agonists

Thiazolidinediones (TZDs), which are peroxisome proliferator activated receptor (PPAR)-gamma agonists, can cause dose-related fluid retention, when used in combination with insulin. Fluid retention may lead to or exacerbate heart failure. Patients treated with insulin, including ONSWIK and a PPAR-gamma agonist should be observed for signs and symptoms of heart failure. If heart failure develops, it should be managed according to current standards of care and discontinuation or dose reduction of the PPAR-gamma agonist must be considered.

6 ADVERSE REACTIONS

The following adverse reactions are described below or elsewhere in the prescribing information:

- Hypoglycemia Due to Medication Errors and Accidental Overdose [see *Warnings and Precautions* (5.1)].
- Severe Hypoglycemia in Patients with Type 1 Diabetes Mellitus [see *Warnings and Precautions* (5.2)].
- Hypoglycemia [see *Warnings and Precautions* (5.3)].
- Hypersensitivity Reactions [see *Warnings and Precautions* (5.5)].
- Hypokalemia [see *Warnings and Precautions* (5.6)].

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety of ONSWIK was evaluated in four clinical trials involving 1,883 adults with type 2 diabetes mellitus exposed to ONSWIK, with a mean exposure duration of 372 days [see *Clinical Studies* (14)]. The mean age was 59 years, the mean duration of diabetes was 13 years, 55% were male, 63% were White, 21% were Asian, 10% were American Indian or Alaska Native, 5% were Black or African American, and 45% were Hispanic. The mean BMI was 31 kg/m² and the mean HbA1c at baseline was 8.1%.

Common Adverse Reactions

Hypoglycemia

Hypoglycemia is the most common adverse reaction in patients using insulin, including ONSWIK. The frequency of reported hypoglycemia depends on the definition of hypoglycemia used, diabetes type, insulin dose, intensity of glucose control, background therapies, and other intrinsic and extrinsic patient factors. For these reasons, comparing the frequency of hypoglycemia in clinical trials for ONSWIK with the frequency of hypoglycemia for other products may be misleading and may not be representative of hypoglycemia frequencies that occur in clinical practice.

In clinical trials [see *Clinical Studies* (14)], events of severe hypoglycemia (level 3) were defined as an episode associated with severe cognitive impairment requiring external assistance for recovery. Hypoglycemia episodes with a glucose level below 54 mg/dL with or without associated symptoms (level 2 hypoglycemia) were also assessed in patients with type 2 diabetes mellitus.

In clinical trials in patients with type 2 diabetes mellitus, the proportions of adults treated with ONSWIK who experienced at least one episode of level 3 and/or level 2 hypoglycemia in clinical trials are shown in Table 4.

Table 4: Proportion (%) of Patients with Type 2 Diabetes Mellitus Experiencing at Least One Episode of Level 3 (Severe) and/or Level 2 Hypoglycemia in Clinical Trials

	Trial 1 Insulin Naïve Adults on Fixed- Dosage Titration (0-52 weeks) N=397	Trial 2 Insulin Naïve Adults on Flexible-Dosage Titration (0-52 weeks) N=466	Trial 3 Adults Previously Treated with Daily Basal Insulin (0-78 weeks) N=655	Trial 4 Adults Previously Treated with Daily Basal and Mealtime Insulin (0-26 weeks) N=365
Level 3 hypoglycemia ^a	0.3	0	0.9	1.4
Level 3 and/or Level 2 hypoglycemia ^b	25.9	27.9	40.9	55.6

^a Level 3 hypoglycemia: episode associated with severe cognitive impairment requiring external assistance for recovery.

^b Level 2 hypoglycemia: an episode where a self-measured glucose was below 54 mg/dL, with or without the presence of hypoglycemic symptoms.

Insulin Initiation and Intensification of Glucose Control

Intensification or rapid improvement in glucose control has been associated with a transitory, reversible ophthalmologic refraction disorder, worsening of diabetic retinopathy, and acute painful peripheral neuropathy. However, long-term glycemic control decreases the risk of diabetic retinopathy and neuropathy.

Allergic Reactions

Severe, life-threatening, generalized allergy, including anaphylaxis, generalized skin reactions, angioedema, bronchospasm, hypotension, and shock may occur with any insulin, including ONSWIK. Hypersensitivity reactions were reported in adults with type 2 diabetes mellitus treated with ONSWIK: contact dermatitis (0.7%), rash (0.7%), dermatitis (0.7%), hypersensitivity (0.6%), pruritus (0.6%), eczema (0.6%) and allergic rhinitis (0.5%).

Lipodystrophy

Long-term use of insulin, including ONSWIK, can cause lipodystrophy at the site of repeated insulin injections. Lipodystrophy includes lipohypertrophy (thickening of adipose tissue) and lipoatrophy (thinning of adipose tissue) and may affect insulin absorption [see *Dosage and Administration* (2.2)]. Lipodystrophy was reported in 0.3% of adults with type 2 diabetes mellitus treated with ONSWIK.

Injection Site Reactions

Adults with type 2 diabetes mellitus taking ONSWIK have experienced redness, hardening, pain, bruising, swelling or itching at the site of ONSWIK injection.

Injection site reactions occurred in 1.4% of adults with type 2 diabetes mellitus treated with ONSWIK. No patients treated with ONSWIK in the clinical trials discontinued ONSWIK due to injection site-related reactions.

Weight Gain

Weight gain can occur with insulin therapy, including ONSWIK, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria. Adults with type 2 diabetes mellitus treated with ONSWIK with or without mealtime insulin

therapy gained an average of 1.9 to 3.2 kg after 26 weeks of treatment. Adults with type 2 diabetes mellitus treated with ONSWIK without mealtime insulin therapy gained an average of 2.1 to 3.9 kg after 52 weeks of treatment.

Peripheral Edema

ONSWIK may cause sodium retention and edema. Peripheral edema occurred in 1.6% of adults with type 2 diabetes mellitus treated with ONSWIK.

7 DRUG INTERACTIONS

Table 5 includes clinically significant drug interactions with ONSWIK.

Table 5: Clinically Significant Drug Interactions with ONSWIK

Drugs That May Increase the Risk of Hypoglycemia	
Drugs:	Antidiabetic agents (including glucagon-like peptide-1 (GLP-1) receptor agonists, glucose-dependent insulintropic polypeptide (GIP) and GLP-1 receptor agonists, and sodium-glucose co-transporter 2 (SGLT2) inhibitors), angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor blocking agents, disopyramide, fibrates, monoamine oxidase inhibitors, pentoxifylline, salicylates, selective serotonin re-uptake inhibitors (SSRIs), somatostatin analogs, and sulfonamide antibiotics.
Intervention:	Dose reductions of ONSWIK and increased frequency of glucose monitoring may be required when ONSWIK is co-administered with these drugs.
Drugs That May Decrease the Glucose-Lowering Effect of ONSWIK	
Drugs:	Atypical antipsychotics (e.g., olanzapine and clozapine), corticosteroids, danazol, diazoxide, diuretics, estrogens, glucagon, isoniazid, niacin, oral contraceptives, pasireotide, phenothiazine, protease inhibitors, somatropin, sympathomimetic agents (e.g., albuterol, epinephrine, and terbutaline), and thyroid hormones.
Intervention:	Dose increases of ONSWIK and increased frequency of glucose monitoring may be required when ONSWIK is co-administered with these drugs.
FcRn Inhibitors:	Neonatal Fc receptor (FcRn) inhibitors (for example, efgartigimod, rozanolixizumab, nipocalimab) may lower systemic exposure of ONSWIK and reduce its effectiveness.
Intervention:	If treatment with an FcRn inhibitor is required, consider switching to an alternative basal insulin.
Drugs That May Increase or Decrease the Glucose-Lowering Effect of ONSWIK	
Drugs:	Alcohol, beta-blockers, clonidine, lithium salts, and octreotide or lanreotide. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia.
Intervention:	Dose adjustment of ONSWIK and increased frequency of glucose monitoring may be required when ONSWIK is co-administered with these drugs.
Drugs That May Blunt Signs and Symptoms of Hypoglycemia	
Drugs:	Beta-blockers, clonidine, guanethidine, and reserpine.
Intervention:	Increased frequency of glucose monitoring may be required when ONSWIK is co-administered with these drugs.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

The use of ONSWIK during pregnancy is not recommended.

Available data with ONSWIK use in pregnant women are insufficient to evaluate for a drug-related risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy (*see Clinical Considerations*). Based on animal reproduction studies, there may be risks to the fetus from exposure to ONSWIK during pregnancy.

In pregnant rats or rabbits administered insulin efsitora alfa-gobe during organogenesis, early embryonic deaths, and fetal abnormalities occurred at clinically relevant exposures at the maximum recommended human dose (MRHD) of 1,400 units /week and were associated with hypoglycemia in maternal non-diabetic animals. Hypoglycemia-related mortality occurred in rats during pregnancy and following birth, and pup mortality occurred during the lactation period,

which correlated with plasma exposure levels of insulin efsitora alfa-gobe and severe hypoglycemia in pups. Human IgG is known to cross the placental barrier via FcRn transfer; therefore, insulin efsitora alfa-gobe may be transmitted from the mother to the developing fetus in late pregnancy.

The estimated background risk of major birth defects is 6% to 10% in women with pre-gestational diabetes with a HbA1c >7% and has been reported to be as high as 20% to 25% in women with a HbA1c >10%. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-associated Maternal and/or Embryo-Fetal Risk

Poorly controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery, and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related morbidity.

Data

Animal Data

In pregnant rats, insulin efsitora alfa-gobe did not cause adverse effects on embryo-fetal development when given subcutaneously during organogenesis at doses of 22 and 75 units/kg/week, which were up to 0.2-fold the MRHD, based on AUC. However, increased post-implantation loss secondary to maternal hypoglycemia was observed when rats were given 75 units/kg/week insulin efsitora alfa-gobe prior to and during mating and through early gestation (Gestation Day 6) at clinically relevant exposures.

In pregnant rabbits given subcutaneous doses during organogenesis of 6 and 22 units/kg/week insulin efsitora alfa-gobe weekly, which were up to 0.1-fold the MRHD, post-implantation losses and fetal skeletal/visceral abnormalities were observed at clinically relevant exposures, which were secondary to maternal hypoglycemia.

In a pre- and postnatal developmental study in rats where insulin efsitora alfa-gobe was given subcutaneously from implantation through the end of lactation (Gestation Day 6 through Lactation Day 20) at doses of 22 and 75 units/kg/week, which were up to 0.6-fold the MRHD, hypoglycemia-related maternal mortality during or following birth and pup mortality during the lactation period occurred at clinically relevant exposures. There was plasma exposure of insulin efsitora alfa-gobe and severe hypoglycemia in pups, which is likely due to FcRn-mediated transfer of insulin efsitora alfa-gobe.

8.2 Lactation

Risk Summary

The use of ONSWIK during breastfeeding or lactation is not recommended.

There are no data on the presence of insulin efsitora alfa-gobe in animal or human milk, the effects on the breastfed infant, or the effects on milk production. Based on plasma exposure levels of insulin efsitora alfa-gobe in rat pups, there is indirect evidence of presence of insulin efsitora alfa-gobe in the milk.

8.4 Pediatric Use

Safety and effectiveness of ONSWIK have not been established in pediatric patients.

ONSWIK is not recommended for use in pediatric patients with type 1 diabetes mellitus due to increased risk of severe hypoglycemia [see *Indications and Usage (1) and Warnings and Precautions (5.2)*].

8.5 Geriatric Use

In clinical trials, 30% (561/1,883) of ONSWIK-treated patients were 65 years of age or older, and 5% (85/1,883) of ONSWIK-treated patients were 75 years of age or older at baseline. No overall differences in safety or effectiveness of ONSWIK have been observed between patients 65 years of age and older and younger adult patients.

Greater caution should be exercised when ONSWIK is administered to geriatric patients since greater sensitivity of some older individuals to the effects of ONSWIK cannot be ruled out. The initial dosing, dose increments, and maintenance dosage should be conservative to avoid hypoglycemia. Hypoglycemia may be more difficult to recognize in the elderly. More frequent glucose monitoring is recommended, and the insulin dose is to be adjusted on an individual basis.

8.6 Renal Impairment

No clinically relevant differences in the pharmacokinetics of insulin efsitora alfa-gobe were observed across the different renal impairment subgroups [see *Clinical Pharmacology* (12.3)]. Additional dose adjustment should not be necessary for patients with renal impairment. However, as with all insulin products, glucose monitoring should be intensified and the ONSWIK dosage adjusted on an individual basis in patients with renal impairment.

8.7 Hepatic Impairment

No difference in the pharmacokinetics of ONSWIK was identified comparing healthy subjects and subjects with hepatic impairment [see *Clinical Pharmacology* (12.3)]. Additional dose adjustment should not be necessary for patients with hepatic impairment. However, as with all insulin products, glucose monitoring should be intensified and the ONSWIK dosage adjusted on an individual basis in patients with hepatic impairment.

10 OVERDOSAGE

Overdosage of insulin may cause hypoglycemia with accompanying symptoms that include listlessness, confusion, palpitations, sweating, vomiting, and headache.

Hypoglycemia and hypokalemia may occur as a result of an excess of ONSWIK relative to food intake, energy expenditure, or both [see *Warnings and Precautions* (5.3, 5.6)]. Mild episodes of hypoglycemia usually can be treated with oral carbohydrates. Lowering the dosage of ONSWIK, adjustments in meal patterns, or physical activity may be needed.

More severe episodes with coma, seizure, or neurologic impairment may be treated with glucagon or concentrated intravenous glucose. Sustained carbohydrate intake and observation may be necessary, because hypoglycemia may recur after apparent clinical recovery. Hypokalemia must be corrected appropriately.

Consideration of the prolonged duration of action of ONSWIK is recommended in the management of overdose [see *Dosage and Administration* (2.6), *Warnings and Precautions* (5.3), *Clinical Pharmacology* (12.2)].

11 DESCRIPTION

Insulin efsitora alfa-gobe is a long-acting insulin analog that is divalent (dimer), consisting of a single-chain insulin (comprised of insulin B-chain analog, a short peptide linker, and an insulin A-chain analog) fused to a second peptide linker that is fused to a human IgG2 Fc region. Each monomer is comprised of 299 amino acid residues. Insulin efsitora alfa-gobe is produced using Chinese Hamster Ovary cells by recombinant DNA technology. The molecule contains 24-Cys residues that are involved in 2 interchain and 10 intrachain disulfide bonds. The predominant post-translational modification includes N-linked glycosylation of the heavy chain (Asn150). The molecular weight of insulin efsitora alfa-gobe is approximately 64 kDa.

ONSWIK (insulin efsitora alfa-gobe) injection is a clear and colorless to yellow solution for subcutaneous use.

ONSWIK injection is a sterile, preserved formulation supplied in two concentrations (500 units/mL or 1,000 units/mL) manufactured for use in a prefilled pen.

Each mL of ONSWIK U-500 contains 500 units of insulin efsitora alfa-gobe and the inactive ingredients benzyl alcohol (9 mg), dibasic sodium phosphate (0.084 mg), glycerin (17 mg), monobasic sodium phosphate (0.53 mg), phenol (1.8 mg), poloxamer 188 (0.4 mg), and Water for Injection. The 500 units/mL cartridge delivers 5 units of ONSWIK per 0.01 mL (14.3 mg/mL).

Each mL of ONSWIK U-1,000 contains 1,000 units of insulin efsitora alfa-gobe and the inactive ingredients benzyl alcohol (9 mg), dibasic sodium phosphate (0.168 mg), glycerin (17 mg), monobasic sodium phosphate (1.06 mg), phenol (1.8 mg), poloxamer 188 (0.4 mg), and Water for Injection. The 1,000 units/mL cartridge delivers 10 units of ONSWIK per 0.01 mL (28.6 mg/mL).

Hydrochloric acid, glacial acetic acid and/or sodium hydroxide may be added to adjust the pH. ONSWIK has a pH of approximately 6.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The primary activity of ONSWIK is the regulation of glucose metabolism. Insulin and its analogs lower blood glucose by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin also inhibits lipolysis and proteolysis and enhances protein synthesis.

The protracted time-action profile of ONSWIK results from reduced renal clearance due to its relatively large molecular size, inhibition of degradation due to binding at the neonatal Fc receptor, and reduced affinity relative to human insulin for the insulin receptor, which decreases receptor-mediated clearance. Once insulin efsitora alfa-gobe is engaged with the insulin receptor, it results in the same pharmacological effects as human insulin.

12.2 Pharmacodynamics

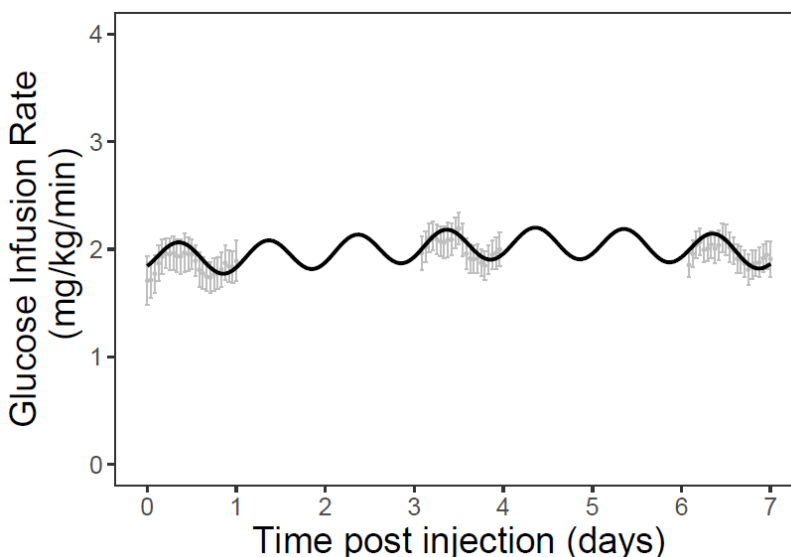
The glucose-lowering effect of ONSWIK at steady-state was measured with a euglycemic glucose clamp study in 53 adults with type 2 diabetes mellitus. The glucose infusion rate (GIR) measured in three euglycemic clamps from 0 to 24 hours, 72 to 96 hours and 144 to 168 hours post dose, along with the model-derived GIR profile show the duration of the glucose lowering effect to cover the weekly dosing interval (see Figure 1).

At steady-state, the mean maximum glucose-lowering effect occurred between Days 4 and 5, with a peak-trough ratio of 1.07. The glucose-lowering response was stable over the dosing interval, with low day-to-day variability of 2% (coefficient of variation for the glucose infusion rate at steady-state).

The glucose-lowering effect of ONSWIK lasted approximately 4 to 6 weeks after the last weekly injection.

Following a dosage adjustment, initial changes in FBG are expected within 1 to 2 weeks, with the full treatment effect of the dosage adjustment occurring in approximately 4 weeks [see *Dosage and Administration* (2.1, 2.3, 2.4), *Warnings and Precautions* (5.4)].

Figure 1: Pharmacodynamic Effect of ONSWIK at Steady-State Following Weekly Subcutaneous Injections of 4 units/kg Weekly Dose in Adults with Type 2 Diabetes Mellitus



Notes: Gray dots are means and bars are standard errors of the mean glucose infusion rate (GIR). Black solid line is mean of model-predicted GIR profiles for the weekly dosing interval.

12.3 Pharmacokinetics

Absorption

Absorption of insulin efsitora alfa-gobe was evaluated in healthy subjects and adults with diabetes.

Steady-state pharmacokinetics (PK) was achieved between the eighth and tenth weeks after initiating ONSWIK without a one-time starting dose and between the fourth and sixth weeks after initiating ONSWIK with a one-time starting dose of 3 times the weekly dose [see *Dosage and Administration* (2.3, 2.4)].

At steady-state, time to maximum insulin efsitora alfa-gobe concentration was achieved at 2.5 days post dose (T_{max}). ONSWIK has a peak-to-trough ratio of 1.16 and the week-to-week variability (CV%) in total exposure of ONSWIK was 5%.

The absolute bioavailability of insulin efsitora alfa-gobe after subcutaneous administration into the abdomen, was approximately 86%. Injection site (abdomen, upper arm, or thigh) did not influence the absorption or exposure of ONSWIK.

Total insulin efsitora alfa-gobe exposure and maximum insulin efsitora alfa-gobe concentration increased proportionally with increasing subcutaneous doses of ONSWIK within the therapeutic dose range.

No dose conversion is required if transferring a patient between the U-500 and U-1,000 strengths when each is administered at the same units/kg dose.

Distribution

Following a 100-unit subcutaneous bolus injection of ONSWIK, the geometric mean (CV%) volume of distribution of insulin efsitora alfa-gobe (V_d) was 13 L (24%).

Elimination

Following a 100-unit subcutaneous bolus injection of ONSWIK, the geometric mean (CV%) clearance of insulin efsitora alfa-gobe (CL) was 0.02 L/h (24%). The geometric mean (CV%) elimination half-life at steady-state is approximately 17 days (26%), independent of dose.

Specific Populations

No clinically significant differences in the pharmacokinetics of insulin efsitora alfa-gobe were observed based on age (18 to 88 years), sex (56% male and 44% female), race (67% White, 4.7% Black, 8.4% American Indian or Alaska Native, and 19% Asian), renal function (based on race-free CKD-EPI 2021 category) or based on alanine aminotransferase (ALT 5 to 398 U/L) and aspartate aminotransferase (AST 5 to 325 U/L). The effect of hemodialysis with kidney failure or severe hepatic impairment on the pharmacokinetics of insulin efsitora alfa-gobe is unknown. Insulin efsitora alfa-gobe exposure decreased with increasing body weight (43 to 157 kg), but these effects are mitigated by the recommended dosing based on glycemic control.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies (ADA) is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of ADAs in the trials described below with the incidence of ADAs in other studies, including those of ONSWIK.

During the 26- to 78-week treatment periods in four clinical trials in adults with type 2 diabetes mellitus [see *Clinical Studies* (14)], 59/858 (7%) of insulin-naïve and 34/1,016 (3%) of insulin-experienced adults treated with ONSWIK developed treatment-emergent anti-insulin efsitora alfa-gobe antibodies. In these trials, 30/1,874 (2%) of ONSWIK-treated adults developed anti-insulin efsitora alfa-gobe antibodies that cross-reacted with native insulin.

In these trials, 23/1,874 (1%) of ONSWIK-treated adults and 23/93 (25%) of ONSWIK-treated adults with treatment-emergent anti-insulin efsitora alfa-gobe antibodies, had estimated drug clearance that was higher than that observed in patients who were anti-insulin efsitora alfa-gobe antibody-negative. Among these 23 patients, the estimated drug clearance was approximately 5-fold higher than in patients who were anti-insulin efsitora alfa-gobe antibody-negative, and some patients had very low insulin efsitora alfa-gobe concentrations. These patients may require higher dosages of ONSWIK to achieve glycemic control [see *Dosage and Administration* (2.1, 2.3, 2.4)].

Neutralizing antibodies against insulin efsitora alfa-gobe were detected in 18/858 (2%) of insulin-naïve and 7/1,016 (0.7%) of insulin-experienced adults treated with ONSWIK; 18/59 (31%) of insulin-naïve adults and 7/34 (21%) of insulin-experienced adults with treatment-emergent anti-insulin efsitora alfa-gobe antibodies developed neutralizing antibodies. Neutralizing antibodies against native insulin were detected in 15/1,874 (0.8%) of adults treated with ONSWIK.

There were no identified clinically significant effects of anti-insulin efsitora alfa-gobe antibodies on the safety of ONSWIK.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Standard 2-year carcinogenicity studies in animals have not been performed to evaluate the carcinogenic potential of insulin efsitora alfa-gobe. Insulin efsitora alfa-gobe did not demonstrate higher mitogenic potential compared to human insulin as determined through in vitro assessments of receptor binding, receptor activation and cell-based functional assays. In addition, in rat and dog repeat-dose toxicity studies of up to 26 weeks duration, there were no proliferative tissue changes noted in any tissue including the mammary gland. The available nonclinical data do not indicate an increase in carcinogenic potential of insulin efsitora alfa-gobe compared to human insulin.

Genotoxicity testing of insulin efsitora alfa-gobe was not performed.

In a fertility study in male rats, subcutaneous injections up to 75 units/kg/week insulin efsitora alfa-gobe (up to 0.5-fold the MRHD, based on AUC) prior to and through the mating had no effect on mating performance and fertility at clinically relevant exposures at the MRHD. Similarly, mating and fertility were not adversely affected in female rats given subcutaneous doses up to 75 units/kg/week insulin efsitora alfa-gobe (up to 0.4-fold the MRHD) prior to mating through early gestation at clinically relevant exposures at the MRHD.

14 CLINICAL STUDIES

14.1 Overview of Clinical Studies

The effectiveness of ONSWIK administered once weekly to improve glycemic control in adults with type 2 diabetes mellitus and used in combination with common noninsulin antidiabetic medications with or without mealtime insulin was evaluated in four randomized, open-label, treat-to-target, active-controlled trials. ONSWIK was studied in insulin-naïve adults using fixed-dosage titration (Trial 1) and in insulin-naïve adults using flexible-dosage titration (Trial 2), in adults previously treated with once or twice daily basal insulin (Trial 3), and in adults previously treated with daily basal and mealtime insulin (Trial 4).

14.2 ONSWIK in Insulin-Naïve Adults with Type 2 Diabetes Mellitus

Fixed-Dosage Titration

Trial 1 (QWINT-1, NCT05662332) was a 52-week, randomized, open-label, active-controlled, treat-to-target, multinational trial that evaluated the efficacy of once-weekly subcutaneous ONSWIK in 795 insulin-naïve adults with type 2 diabetes mellitus who were inadequately controlled on one to three noninsulin antidiabetic medications with HbA1c of 7% to 10%. Patients were randomized to either once-weekly ONSWIK (N=397) or once-daily subcutaneous insulin glargine (N=398) administered according to the approved labeling. Patients remained on stable doses of one to three of the following noninsulin antidiabetic medications: Dipeptidyl peptidase 4 (DPP-4) inhibitors, sodium-glucose cotransporter 2 (SGLT2) inhibitors, biguanides such as metformin, alpha-glucosidase inhibitors, oral or injectable glucagon-like peptide-1 (GLP-1) receptor agonists, or thiazolidinediones.

The mean age was 56 years, and 50% were male. The mean duration of type 2 diabetes mellitus was 9 years, and the mean BMI was 32 kg/m². Overall, 68% were White, 27% were American Indian/Alaska Native, 3% were Black or African American, 1% were Asian, 0.3% were Native Hawaiian or Other Pacific Islander, and 0.5% reported multiple races; 85% identified as Hispanic or Latino ethnicity.

ONSWIK was initiated at a dosage of 100 units per week and the dosage was escalated every 4 weeks, as needed, to 150, 250, then 400 units per week. Dosage adjustments were based on the median of the three most recent FBG values to achieve a target FBG range of 80 to 130 mg/dL. Patients with a dose reduction in response to hypoglycemia were not allowed to re-escalate to higher fixed doses. After week 16, patients who were treated with the 400 units per week dosage for at least 4 weeks and needed additional dosage adjustments above 400 units per week underwent subsequent dosage adjustment by 20-40 units per week as needed for glycemic control. At week 52, 18.0% of patients were on 100 units, 21.0% were on 150 units, 28.7% were on 250 units, and 8.7% were on 400 units; 23.7% of patients had undergone additional titration beyond 400 units.

Insulin glargine (100 units/mL) was administered at a starting daily dosage of 10 units that was subsequently adjusted on a weekly basis by 3 to 6 units to achieve a target FBG range of 80 to 130 mg/dL and in response to hypoglycemia.

At week 52, treatment with ONSWIK provided a mean reduction in HbA1c that met the pre-specified non-inferiority margin (0.4%) (see Table 6).

Table 6: Results at Week 52 from Trial 1 Comparing ONSWIK to Insulin Glargine in Insulin-Naïve Adults with Type 2 Diabetes Mellitus Also Receiving Noninsulin Antidiabetic Medications

	ONSWIK	Insulin Glargine
Randomized Population (N)	397	398
HbA1c (%)		
Baseline	8.2	8.3
Week 52 Endpoint ^{a,b}	7.1	7.1
Change at Week 52 ^b	-1.2	-1.1
Difference from insulin glargine (95% CI) ^{b,c}	0.0 (-0.2, 0.1)	
Fasting Serum Glucose (mg/dL)		
Baseline	162	161
Week 52 Endpoint ^b	118	118
Change at Week 52 ^b	-44	-43
Insulin Dose (Units/week)		
Week 52 Dose ^{d,e}	303	333

^a At Week 52, HbA1c data were missing for 10.6% and 9.5% of patients treated with ONSWIK and insulin glargine, respectively.

^b Least-squares mean from ANCOVA adjusted for baseline value and other stratification factors. Missing Week 52 data were imputed using return to baseline multiple imputation.

^c Tested for noninferiority.

^d Least-squares mean from ANOVA adjusted for stratification factors. Missing Week 52 data were imputed using reference-based multiple imputation.

^e Approximately equal to daily ONSWIK dose of 43 units/day or a daily insulin glargine dose of 48 units/day.

Flexible-Dosage Titration

Trial 2 (QWINT-2, NCT05362058) was a 52-week, randomized, open-label, active-controlled, treat-to-target, multinational trial that evaluated the efficacy of once-weekly subcutaneous ONSWIK in 928 insulin-naïve adults with type 2 diabetes mellitus who were inadequately controlled on one to three noninsulin antidiabetic medications with HbA1c of 7% to 10.5%. Patients were randomized to either once-weekly ONSWIK (N=466) or once-daily subcutaneous insulin degludec (N=462) administered according to the approved labeling. Patients remained on stable dosages of one to three of the following noninsulin antidiabetic medications: DPP-4 inhibitors, SGLT2 inhibitors, biguanides such as metformin, alpha-glucosidase inhibitors, oral or injectable GLP-1 receptor agonists, sulfonylureas, or thiazolidinediones.

The mean age was 57 years, and 59% were male. The mean duration of type 2 diabetes mellitus was 12 years, and the mean BMI was 31 kg/m². Overall, 50% were White, 35% were Asian, 8% were American Indian/Alaska Native, 6% were Black or African American, and 0.5% reported multiple races; 26% identified as Hispanic or Latino ethnicity.

ONSWIK was initiated at a one-time starting dosage of 300 units, followed by a weekly dose of 100 units that was subsequently adjusted on a weekly basis by 20 to 40 units to achieve a target FBG range of 80 to 120 mg/dL and in response to hypoglycemia. For patients with a baseline FBG ≤120 mg/dL, a one-time starting dose was not used; ONSWIK was initiated at 100 units. If there was a documented blood glucose ≤70 mg/dL in the previous week, the dose was not increased.

Insulin degludec was administered at a starting daily dosage of 10 units that was subsequently adjusted on a weekly basis by 3 to 6 units to achieve a target FBG range of 80 to 120 mg/dL and in response to hypoglycemia.

At Week 52, treatment with ONSWIK provided a mean reduction in HbA1c that met the pre-specified non-inferiority margin (0.4%) (see Table 7).

Percent time in glucose range (%TIR, 70-180 mg/dL) at baseline was 39.2% for the ONSWIK group and 38.4% for the insulin degludec group. The estimated mean change from baseline in %TIR during the last 4 weeks of the trial (Week 48 to 52) was 24.5% for ONSWIK and 21.4% for insulin degludec. Patients in China were excluded from this analysis.

Table 7: Results at Week 52 from Trial 2 Comparing ONSWIK to Insulin Degludec in Insulin-Naïve Adults with Type 2 Diabetes Mellitus Also Receiving Noninsulin Antidiabetic Medications

	ONSWIK	Insulin Degludec
Randomized Population (N)	466	462
HbA1c (%)		
Baseline	8.2	8.2
Week 52 Endpoint ^{a,b}	7.0	7.1
Change at Week 52 ^b	-1.2	-1.2
Difference from insulin degludec ^{b,c} (95% CI)	-0.1 (-0.2, 0.0)	
HbA1c (%) Patients on GLP-1 Receptor Agonists, N (%)	232 (49.8)	232 (50.2)
Baseline	8.2	8.3
Week 52 Endpoint ^b	7.0	7.0
Change at Week 52 ^b	-1.2	-1.2
Difference from insulin degludec (95% CI) ^{b,c}	-0.1 (-0.3, 0.1)	
HbA1c (%) Patients Not on GLP-1 Receptor Agonists, N (%)	234 (50.2)	230 (49.8)
Baseline	8.2	8.2
Week 52 Endpoint ^b	7.0	7.1
Change at Week 52 ^b	-1.2	-1.1
Difference from insulin degludec (95% CI) ^{b,c}	-0.1 (-0.3, 0.1)	
Fasting Serum Glucose (mg/dL)		
Baseline	162	165
Week 52 Endpoint ^b	108	112
Change at Week 52 ^b	-56	-52
Insulin Dose (Units/week)		
Week 52 Dose ^{d,e}	315	338

^a At Week 52, the HbA1c data were missing for 6.9% and 6.9% of patients treated with ONSWIK and insulin degludec, respectively.

^b Least-squares mean from ANCOVA adjusted for baseline value and other stratification factors. Missing Week 52 data were imputed using return to baseline multiple imputation.

^c Tested for noninferiority.

^d Least-squares mean from ANOVA adjusted for stratification factors. Missing Week 52 data were imputed using reference-based multiple imputation.

^e Approximately equal to a daily ONSWIK dose of 45 units/day or a daily insulin degludec dose of 48 units/day.

14.3 ONSWIK in Adults with Type 2 Diabetes Mellitus Previously Treated with Once- or Twice-Daily Basal Insulin

Trial 3 (QWINT-3, NCT05275400) was a 78-week, randomized, open-label, active-controlled, treat-to-target, multinational trial that evaluated the efficacy of once-weekly subcutaneous ONSWIK in 986 adults with type 2 diabetes mellitus on once- or twice-daily subcutaneous basal insulin therapy alone or in combination with noninsulin antidiabetic medication(s) with a HbA1c of 6.5% to 10%. Patients were randomized in a 2:1 ratio to either once-weekly ONSWIK (N=655) or once-daily insulin degludec (N=331) administered according to the approved labeling. Patients remained on stable doses of up to three of the following noninsulin antidiabetic medications: DPP-4 inhibitors, SGLT2 inhibitors, biguanides such as metformin, alpha-glucosidase inhibitors, or GLP-1 receptor agonists. The primary endpoint was assessed at Week 26.

The mean age was 61 years, and 56% were male. The mean duration of type 2 diabetes mellitus was 15 years, and the mean BMI was 30 kg/m². Overall, 67% were White, 28% were Asian, 5% were Black or African American; 0.2% were American Indian or Alaskan Native, 0.1% were Native Hawaiian or Other Pacific Islander, and 0.3% reported multiple races; 27% identified as Hispanic or Latino ethnicity.

ONSWIK was initiated at a one-time starting dosage calculated by multiplying the prior total daily basal insulin dosage by 7 and then multiplying by 3. For patients with a baseline FBG ≤ 120 mg/dL, a one-time starting dosage was not

recommended; the initial ONSWIK dosage was the prior total basal insulin dose multiplied by 7. The second weekly dosage was the prior total daily basal insulin dose multiplied by 7 then the dosage was subsequently adjusted on a weekly basis by 20 to 40 units to achieve a target FBG range of 80 to 120 mg/dL and in response to hypoglycemia. If there was a documented blood glucose ≤ 70 mg/dL in the previous week, the dose was not increased.

Insulin degludec was initiated at the prior total daily basal insulin dosage then was subsequently adjusted on a weekly basis by 2 to 6 units to achieve a target FBG range of 80 to 120 mg/dL and in response to hypoglycemia.

At week 26, treatment with ONSWIK provided a mean reduction in HbA1c that met the pre-specified non-inferiority margin (0.4%) (see Table 8).

Percent time in glucose range (%TIR, 70-180 mg/dL) at baseline was 52.1% for the ONSWIK group and 52.8% for the insulin degludec group. The estimated mean change from baseline in %TIR during the last 4 weeks of the trial (Week 22 to 26) was 8.9% for ONSWIK and 8.4% for insulin degludec.

Table 8: Results from Trial 3 Comparing ONSWIK to Insulin Degludec in Adults with Type 2 Diabetes Mellitus Also Receiving Noninsulin Antidiabetic Medications (All Patients Previously Treated with Once- or Twice-Daily Basal Insulin)

	ONSWIK	Insulin Degludec
Randomized Population (N)	655	331
HbA1c (%)		
Baseline	7.8	7.8
Week 26 Endpoint ^{a,b}	7.0	7.1
Change at Week 26 ^b	-0.8	-0.7
Difference from insulin degludec (95% CI) ^{b,c}	-0.1 (-0.2, 0.0)	
Fasting Serum Glucose (mg/dL)		
Baseline	136	136
Week 26 Endpoint ^b	107	109
Change at Week 26 ^b	-29	-27
Insulin Dose (Units/week)		
Baseline	232	227
Week 26 Dose ^{b,d}	333	363
Change from Baseline to Week 26 ^b	103	133
Week 78 Dose ^{b,e}	343	386
Change from Baseline to Week 78 ^b	113	156

^a At Week 26, the HbA1c data were missing for 4.6% and 5.4% of patients treated with ONSWIK and insulin degludec, respectively.

^b Least-squares mean from ANCOVA adjusted for baseline value and other stratification factors. Missing Week 26 and Week 78 data were imputed using return to baseline multiple imputation.

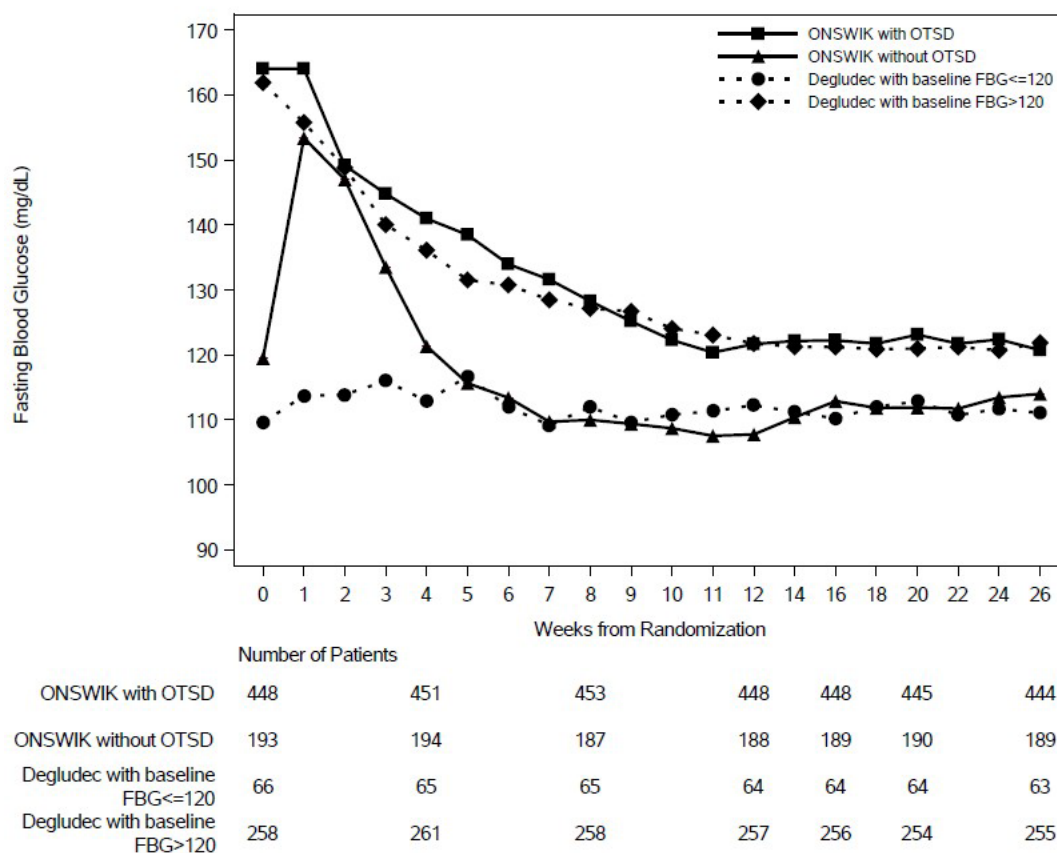
^c Tested for noninferiority.

^d Approximately equal to a daily ONSWIK dose of 48 units/day or a daily insulin degludec dose of 52 units/day at Week 26.

^e Approximately equal to a daily ONSWIK dose of 49 units/day or a daily insulin degludec dose of 55 units/day at Week 78.

Figure 2 illustrates the differences in the trajectory of mean FBG over time between patients who initiated ONSWIK with a one-time starting dose (FBG >120 mg/dL) and without a one-time starting dose (FBG ≤ 120 mg/dL) compared with patients with similar baseline FBG cut-off values at randomization treated with daily insulin degludec during Trial 3. The cohort that did not receive the one-time starting dose of ONSWIK experienced a transient rise in FBG from baseline over the first week of therapy which then declined over the following 4 to 6 weeks and stabilized [see *Dosage and Administration* (2.4), *Warnings and Precautions* (5.4)].

Figure 2: Mean Fasting Blood Glucose over Time from Trial 3 Comparing ONSWIK to Insulin Degludec in Adults with Type 2 Diabetes Mellitus Also Receiving Noninsulin Antidiabetic Medications (All Patients Previously Treated with Once- or Twice-Daily Basal Insulin)



OTSD, one-time starting dose.

Notes: This figure separates the ONSWIK patients into two groups: those who received the one-time starting dose and those who did not. The one-time starting dose was not recommended for patients with baseline FBG ≤120 mg/dL. The degludec patients were separated into two groups: baseline FBG <120 mg/dL and baseline FBG ≥120 mg/dL.

14.4 ONSWIK in Adults with Type 2 Diabetes Mellitus Previously Treated with Once- or Twice-Daily Basal Insulin and Mealtime Insulin

Trial 4 (QWINT-4, NCT05462756) was a 26-week, randomized, open-label, active-controlled, treat-to-target, multinational trial that evaluated the efficacy of once-weekly subcutaneous ONSWIK in 730 adults with type 2 diabetes mellitus on once- or twice-daily basal insulin and mealtime insulin with a HbA1c of 7% to 10%. Patients were randomized to either once-weekly ONSWIK (N=365) or once-daily insulin glargine (N=365) administered according to the approved labeling. Patients remained on stable doses of up to three of the following noninsulin antidiabetic medications: DPP-4 inhibitors, SGLT2 inhibitors, biguanides such as metformin, or GLP-1 receptor agonists. During the randomized treatment period, patients also received mealtime insulin lispro.

The mean age was 59 years, and 50% were male. The mean duration of type 2 diabetes mellitus was 17 years, and the mean BMI was 32 kg/m². Overall, 69% were White, 14% were Asian, 13% were American Indian or Alaskan Native, and 4% were Black or African American; 55% identified as Hispanic or Latino ethnicity.

ONSWIK was initiated at a one-time starting dose calculated by multiplying the prior total daily basal insulin dosage by 7 and then multiplying by 3. For patients with a baseline FBG ≤120 mg/dL, a one-time starting dosage was not recommended; the initial ONSWIK dosage was the prior total daily basal insulin dose multiplied by 7. The second weekly dosage was the prior total daily basal insulin dose multiplied by 7 and was subsequently adjusted on a weekly basis by 20 to 40 units to achieve a target FBG range of 80 to 120 mg/dL and in response to hypoglycemia. If there was a documented blood glucose ≤70 mg/dL in the previous week, the dose was not increased.

Insulin glargine was initiated at the prior total daily basal insulin dosage and was subsequently adjusted on a weekly basis by 3 to 6 units to achieve a target FBG range of 80 to 120 mg/dL and in response to hypoglycemia.

At week 26, treatment with ONSWIK provided a mean reduction in HbA1c that met the pre-specified non-inferiority margin (0.4%) (see Table 9).

Percent time in glucose range (%TIR, 70-180 mg/dL) at baseline was 44.0% for the ONSWIK group and 43.3% for the insulin glargine group. The estimated mean change from baseline in %TIR during the last 4 weeks of the trial (Week 22 to 26) was 14.4% for ONSWIK and 13.1% for insulin glargine.

Table 9: Results at Week 26 from Trial 4 Comparing ONSWIK to Insulin Glargine in Adults with Type 2 Diabetes Mellitus Also Receiving Noninsulin Antidiabetic Medications and Mealtime Insulin Lispro (All Patients Previously Treated with Once- or Twice-Daily Basal Insulin and Mealtime Insulin)

	ONSWIK	Insulin Glargine
Randomized Population (N)	365	365
HbA1c (%)		
Baseline	8.2	8.2
Week 26 Endpoint ^{a,b}	7.2	7.2
Change at Week 26 ^b	-1.0	-1.0
Difference from insulin glargine (95% CI) ^{b,c}	0.0 (-0.1, 0.1)	
Fasting Serum Glucose (mg/dL)		
Baseline	148	153
Week 26 Endpoint ^b	117	130
Change at Week 26 ^b	-33	-21
Basal Insulin Dose (Units/week)		
Baseline	250	249
Dose at Week 26 ^{b,d}	374	413
Change from Baseline ^b	125	164
Mealtime Insulin Dose (Units/day)		
Baseline	26	28
Week 26 Dose ^b	27	32
Change from Baseline ^b	-0.3	5

^a At Week 26, the HbA1c data were missing for 5.8% and 7.1% of patients treated with ONSWIK and insulin glargine, respectively.

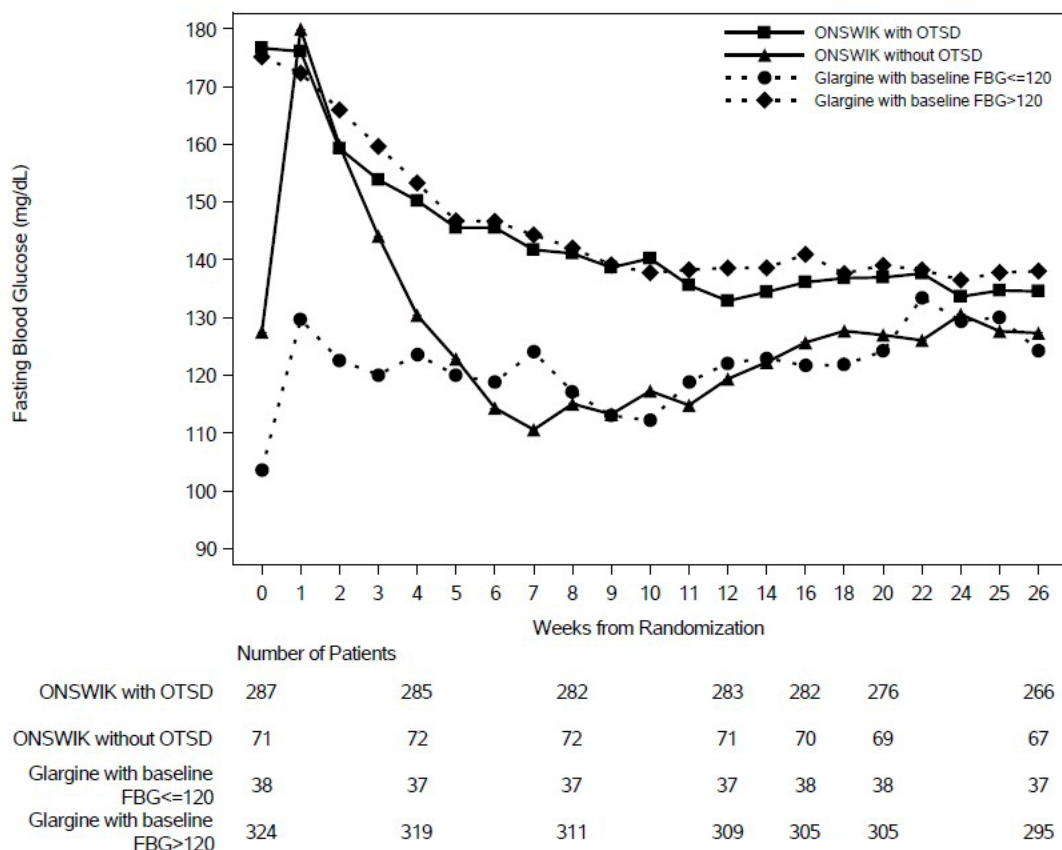
^b Least-squares mean from ANCOVA adjusted for baseline value and other stratification factors. Missing Week 26 data were imputed using return to baseline multiple imputation.

^c Tested for noninferiority.

^d Approximately equal to a daily ONSWIK dose of 53 units/day or a daily insulin glargine dose of 59 units/day.

Figure 3 illustrates the differences in the trajectory of mean FBG over time between patients who initiated ONSWIK with a one-time starting dose (FBG >120 mg/dL) and without a one-time starting dose (FBG ≤120 mg/dL) compared with patients with similar baseline FBG cut-off values at randomization treated with daily insulin glargine during Trial 4. The cohort that did not receive the one-time starting dose of ONSWIK experienced a transient rise in FBG from baseline over the first week of therapy which then declined over the following 4 to 6 weeks and stabilized [see *Dosage and Administration* (2.4), *Warnings and Precautions* (5.4)].

Figure 3: Mean Fasting Blood Glucose over Time for Trial 4 Comparing ONSWIK to Insulin Glargine in Adults with Type 2 Diabetes Mellitus Also Receiving Noninsulin Antidiabetic Medications and Mealtime Insulin Lispro (All Patients Previously Treated with Once- or Twice-Daily Basal Insulin and Mealtime Insulin)



OTSD, one-time starting dose.

Notes: This figure separates the ONSWIK patients into two groups: those who received the one-time starting dose and those who did not. The one-time starting dose was not recommended for patients with baseline FBG ≤120 mg/dL. The glargine patients were separated into two groups: baseline FBG <120 mg/dL and baseline FBG ≥120 mg/dL.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

ONSWIK (insulin efsitora alfa-gobe) injection is a clear, colorless to yellow solution available in the presentations shown in Table 10.

Table 10: Presentations of ONSWIK

ONSWIK Presentation	Concentration	Total Units in Presentation	Maximum Dose per Injection	Dose Increment	NDC Number	Package Size
3 mL U-500 KwikPen	500 units/mL	1,500 units	400 units	5 units	0002-5137-11	1 pen
3 mL U-1,000 KwikPen	1,000 units/mL	3,000 units	800 units	10 units	0002-5240-11	1 pen

16.2 Storage and Handling

- Dispense in the original sealed carton with the enclosed Instructions for Use.
- Store ONSWIK refrigerated at 2°C to 8°C (36°F to 46°F) at all times.

- Do not store your pen with the needle attached.
- If refrigeration is unavailable, the pen can be stored at room temperature up to 30°C (86°F) for up to a total of 14 days. Dispose of ONSWIK that has been left at room temperature for longer than 14 days.
- Do not freeze ONSWIK. Do not use ONSWIK if frozen. Keep away from heat and light.
- Use within 112 days (16 weeks) after first use. Discard after 112 days (16 weeks) even if the pen still contains ONSWIK.

The storage conditions for the pens are summarized in Table 11.

Table 11: Storage Conditions for ONSWIK KwikPens

ONSWIK Presentation	Not in-use (Unopened)		In-use ^a (Opened)	
	Refrigerated (2°C to 8°C [36°F to 46°F])	If refrigeration not possible Room Temperature (up to 30°C [86°F]) ^b	Refrigerated (2°C to 8°C [36°F to 46°F])	If refrigeration not possible Room Temperature (up to 30°C [86°F]) ^b
3 mL U-500 KwikPen	Until expiration date	Total of 14 days	112 days (16 weeks)	Total of 14 days
3 mL U-1,000 KwikPen	Until expiration date	Total of 14 days	112 days (16 weeks)	Total of 14 days

^a ONSWIK can only be used for a total of 112 days (16 weeks) of which 14 days can be at room temperature.

^b Combined time outside of refrigeration (unopened or opened) must not exceed 14 days.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Hypoglycemia Due to Medication Errors and Accidental Overdose

Advise patients to always check the product label before each injection to confirm they are using ONSWIK and not another insulin or injectable antidiabetic medicine. Advise patients using other injectable medications for glycemic control that the dosage selection of ONSWIK differs. Instruct patients to visually verify the dialed units on the dose window of the ONSWIK KwikPen before each injection to avoid dosing errors. Instruct patients to not transfer ONSWIK from the prefilled pen to a syringe. The markings on the syringe will not measure the dose correctly and this can result in overdosage and severe hypoglycemia [see *Warnings and Precautions* (5.1)].

Hypoglycemia

Inform patients that hypoglycemia is the most common adverse reaction with insulin. Instruct patients on self-management procedures including glucose monitoring, proper injection technique, and management of hypoglycemia, especially upon initiation of ONSWIK therapy. Instruct patients on handling of special situations such as intercurrent conditions (illness, stress, or emotional disturbances), an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, and skipped meals. [see *Warnings and Precautions* (5.3)].

Inform patients that their ability to concentrate and react may be impaired as a result of hypoglycemia. Advise patients who have frequent hypoglycemia or reduced or absent warning signs of hypoglycemia to use caution when driving or operating machinery [see *Warnings and Precautions* (5.3)].

Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen

Advise patients that changes in insulin regimen can predispose to hyperglycemia or hypoglycemia and that changes in insulin regimen should be made under close medical supervision [see *Warnings and Precautions* (5.4)].

Hypersensitivity Reactions

Advise patients that hypersensitivity reactions have occurred with ONSWIK. Inform patients of the symptoms of hypersensitivity reactions and to seek prompt medical attention if these symptoms occur [see *Warnings and Precautions* (5.5)].

Never Share an ONSWIK Prefilled Pen Between Patients

Advise patients that they must never share an ONSWIK prefilled pen with another person, even if the needle is changed. Sharing poses a risk for transmission of blood-borne pathogens [see *Warnings and Precautions* (5.7)].

Storing the KwikPen

Advise patients to store their ONSWIK KwikPen refrigerated between 2°C to 8°C (36°F to 46°F), even after first use and in between uses. The ONSWIK KwikPen may only be stored for up to a total of 14 days at room temperature not to exceed 30°C (86°F). Instruct patients to discard their ONSWIK KwikPen if kept outside of the refrigerator for a total duration over 14 days [see *How Supplied/Storage and Handling* (16)].

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PATIENT INFORMATION

ONSWIK™ (ON-swihk) **(insulin efsitora alfa-gobe)** **injection, for subcutaneous use**

Do not share your ONSWIK prefilled pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

Make sure you use the right type and dose of insulin. Always check the label on your insulin pen before each injection to avoid mix-ups with ONSWIK and other insulin products or injectable medicines used to treat diabetes. If you use another injectable medicine to treat your diabetes, pay close attention to how you select your ONSWIK dosage. The dosage of ONSWIK is different from other injectable medicines used to treat diabetes.

Always make sure that you select the correct dosage of your ONSWIK KwikPen as prescribed by your healthcare provider, to avoid dosing errors and accidental overdose. People who are blind or have vision problems should not use this pen without help from a person trained to use the pen.

Do not dial the maximum single dosage (400 units or 800 units) of your ONSWIK KwikPen, unless prescribed by your healthcare provider.

Do not use a syringe to withdraw ONSWIK from your pen.

Talk to your healthcare provider if you have any questions about how to correctly dose ONSWIK KwikPen.

What is ONSWIK?

- **ONSWIK is a long-acting man-made insulin that is used with diet and exercise to control high blood sugar in adults with type 2 diabetes mellitus.**
- ONSWIK should not be used by people who have type 1 diabetes mellitus.
- It is not known if ONSWIK is safe and effective in children.
- ONSWIK is available in 2 concentrations (U-500 and U-1,000):
 - U-500 (500 units/mL) prefilled pen can be injected in 5 unit increments and can deliver up to 400 units in a single injection.
 - U-1,000 (1,000 units/mL) prefilled pen can be injected in 10 unit increments and can deliver up to 800 units in a single injection.

Who should not take ONSWIK?

Do not take ONSWIK if you:

- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to insulin efsitora alfa-gobe or any of the ingredients in ONSWIK. See the end of this Patient Information leaflet for a complete list of ingredients in ONSWIK.

Before taking ONSWIK, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems.
- take any other medicines, especially ones called TZDs (thiazolidinediones).
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with ONSWIK.
- are pregnant, planning to become pregnant, or are breastfeeding. It is not known if ONSWIK may harm your unborn or breastfeeding baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Before you start using ONSWIK, talk to your healthcare provider about low blood sugar and how to manage it.

How should I take ONSWIK?

- Read the **Instructions for Use** that come with your ONSWIK KwikPen.
- **Your healthcare provider should show you how to use ONSWIK KwikPen before you use it for the first time.**
- Take ONSWIK exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much ONSWIK to use and when to use it.
- Know the type, strength and amount of insulin you take. **Do not change the type of insulin unless** your healthcare provider tells you to. The amount of insulin and the best time for you to take your insulin may need to change if you take different types of insulin.
- Inject ONSWIK 1 time each week, on the same day of the week.
- If you need to change the day of the week, you may do so if it has been at least 4 days since your last dose. After your injection day has changed continue to inject 1 time each week on the new day you have chosen.
- **If you miss a dose of ONSWIK:**
 - take the missed dose as soon as possible within 4 days (96 hours) after the missed dose, then continue your regular weekly dose schedule
 - If more than 4 days have passed, skip the missed dose and take your next dose on the regularly scheduled day **or** take the missed dose then change your regular weekly dose schedule to start 1 week after your missed dose was injected.
- **If you accidentally take your 1-time starting dose of ONSWIK more than 1 time (2 weeks in a row) or you take your weekly dose more than 1 time in the same week, skip your next week's dose.**
- ONSWIK can be injected under the skin (subcutaneously) of your stomach area (abdomen), buttocks, thigh or back of the upper arms.
- **Do not** use ONSWIK in an insulin pump or inject ONSWIK into your vein (intravenously) or muscle (intramuscularly).

- **Change (rotate) your injection sites within the area you choose with each dose** to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites.
 - **Do not** use the exact same spot for each injection.
 - **Do not** inject where the skin has pits, is thickened, or has lumps.
 - **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- Always use a new needle for each injection to help prevent infections and blocked needles. If your needle is blocked get a new needle as instructed in the Troubleshooting section at the end of the Instructions for Use.
- **Do not reuse or share your needles with other people.** You may give other people a serious infection or get a serious infection from them.
- **Do not** use a syringe to remove the solution from the pen. Using a syringe may cause dosing errors and potential overdose.
- **Do not** dilute or mix ONSWIK with any other type of insulin or liquid medicine.
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugar levels should be and when you should check your blood sugar levels.

Keep ONSWIK and all medicines out of the reach of children.

What should I avoid while taking ONSWIK?

While taking ONSWIK do not:

- drive or operate heavy machinery, until you know how ONSWIK affects you.
- drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

What are the possible side effects of ONSWIK?

ONSWIK may cause serious side effects that can lead to death, including:

- **low blood sugar (hypoglycemia).** Signs and symptoms that may indicate low blood sugar include:

◦ dizziness or light-headedness	◦ blurred vision	◦ sweating
◦ anxiety, irritability, or mood change	◦ slurred speech	◦ hunger
◦ confusion	◦ fast heartbeat	◦ headache
◦ shakiness		
- **severe allergic reactions (whole body reaction).** Stop using ONSWIK and get medical help right away if you have any of these signs or symptoms of a severe allergic reaction:

◦ a rash over your whole body	◦ trouble breathing
◦ a fast heartbeat	◦ sweating
- **low potassium in your blood (hypokalemia).**

- **heart failure.** Taking certain diabetes pills called TZDs with ONSWIK may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure it may get worse while you take TZDs with ONSWIK. Your healthcare provider should monitor you closely while you are taking TZDs with ONSWIK. Tell your healthcare provider if you have any new or worse symptoms of heart failure including:

- shortness of breath
- swelling of your ankles or feet
- sudden weight gain
- tiredness

Treatment with TZDs and ONSWIK may need to be changed or stopped by your healthcare provider if you have new or worse heart failure.

Your insulin dose may need to change because of:

- change in level of physical activity or exercise
- increased stress
- illness
- weight gain or loss
- change in diet
- other medicines you take

The most common side effects of ONSWIK include:

- hypoglycemia, allergic reactions, reactions at the injection site, skin thickening or pits at the injection site (lipodystrophy), itching, rash, swelling of your hands and feet, and weight gain.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, confusion.

These are not all the possible side effects of ONSWIK. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of ONSWIK.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about ONSWIK that is written for health professionals. **Do not** use ONSWIK for a condition for which it was not prescribed. Do not give ONSWIK to other people, even if they have the same symptoms that you have. It may harm them.

What are the ingredients in ONSWIK?

Active ingredients: insulin efsitora alfa-gobe

Inactive ingredients: benzyl alcohol, dibasic sodium phosphate, glycerin, monobasic sodium phosphate, phenol, poloxamer 188 and Water for Injection. Hydrochloric acid, glacial acetic acid and/or sodium hydroxide may have been added to adjust the pH.

ONSWIK™ is a trademark of Eli Lilly and Company.

Manufactured by: Eli Lilly and Company, Indianapolis, IN 46285, USA, US License No. 1891

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For more information, go to www.onswik.lilly.com or call 1-800-545-5979.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Issued: 09/2026

A3.0-ONS-0000-PPI-YYYYMMDD

INSTRUCTIONS FOR USE

ONSWIK™ KwikPen® [ON-swihk KWIHK-pehn]

(insulin efsitora alfa-gobe)

injection, for subcutaneous use

3 mL single-patient-use pen (500 units/mL, U-500)



Important:

- **ONSWIK KwikPen® is used 1 time each week (once weekly).**
- This ONSWIK KwikPen® (Pen) works differently from other pens. It dials 5 insulin units with each click. **Do not count clicks of the dose knob to select your dose. You may get too much insulin or you may not get enough insulin.**
- **Do not transfer ONSWIK insulin from your Pen into a syringe. A severe overdose can happen, causing very low blood sugar, which may put your life in danger.**
- **Know your dose of ONSWIK insulin.** The Pen delivers your dose in **insulin units**. Insulin units may **not be the same** as syringe markings. **Ask your healthcare provider what your dose should be for your Pen.**



**DO NOT TRANSFER TO A SYRINGE
SEVERE OVERDOSE CAN RESULT**

Read this Instructions for Use before you start injecting ONSWIK KwikPen and each time you get another Pen. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

ONSWIK KwikPen ("Pen") is a disposable (can be thrown away) single-patient-use prefilled pen containing 1,500 units of ONSWIK. You can give yourself more than 1 dose from the Pen. Each turn (click) of the Dose Knob dials 5 units of insulin. You can give from 5 units to 400 units in a single injection. **If your dose is more than 400 units, you will need to give yourself more than 1 injection.**

The Plunger only moves a little with each injection, and you may not notice that it moves. The Plunger will only reach the end of the cartridge when you have used all 1,500 units in the Pen. When the Pen is empty, throw away the entire Pen and get a new Pen (see **Throwing away (disposing of) Pens and Needles** section at the end of this Instructions for Use).

ONSWIK KwikPen is used 1 time a week. You may want to mark your calendar to remind yourself when to take your next dose.

Inject ONSWIK only with your Pen. Do not transfer insulin from your Pen to a syringe. A severe overdose can happen, causing very low blood sugar, which may put your life in danger.

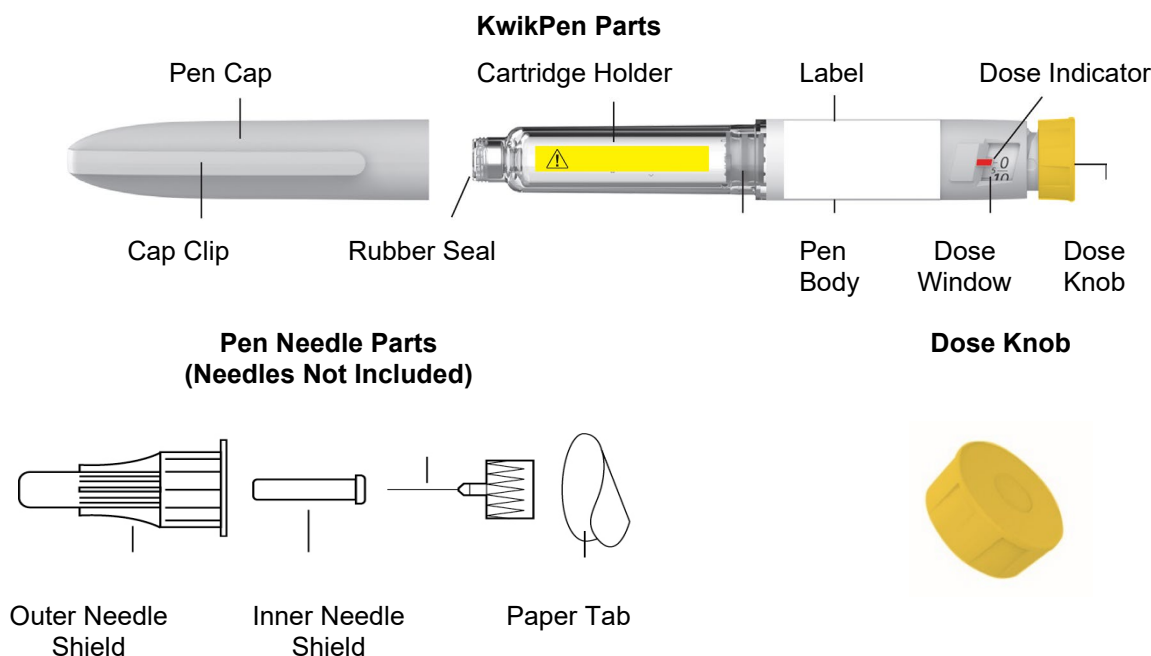
People who are blind or have vision problems should not use the Pen without help from a person trained to use the Pen.

Do not share your ONSWIK KwikPen with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

Storing your Pen

Keep your Pen refrigerated.

- Store the Pen you are currently using in the refrigerator at 36°F to 46°F (2°C to 8°C) at all times.
- If you are not able to refrigerate the Pen, the Pen can be stored at room temperature up to 86°F (30°C) for up to a total of 14 days.
 - **Do not** freeze ONSWIK KwikPen. **Do not** use if it has been frozen.
- Keep away from heat and light.
- If the Pen has been stored in the refrigerator, **throw away the Pen you are using after 112 days (16 weeks), even if it still has ONSWIK in it.**
 - If the Pen has been at room temperature for over 14 days, **throw away** the Pen.
- Do not use your Pen past the expiration date printed on the Label.



How to recognize your ONSWIK KwikPen

- Pen color: Light Gray
- Dose Knob: Yellow
- Label: ONSWIK KwikPen 500 units per mL

500 units/mL

Supplies needed to give your injection

- ONSWIK KwikPen
- KwikPen compatible Needle (29 to 32 gauge needle recommended)
- 1 alcohol swab
- 1 cotton ball or piece of gauze
- 1 FDA-cleared sharps disposal container

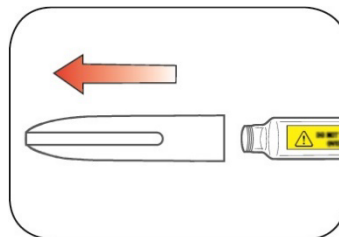
Preparing your Pen

- Wash your hands with soap and water.
- Check the Pen to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- **Do not** use your Pen past the expiration date printed on the Label or for more than 112 days (16 weeks) after you first start using the Pen.
- **Always use a new Needle for each injection to help prevent infections and blocked Needles. Do not reuse or share your needles with other people. You may give other people a serious infection or get a serious infection from them.**

Step 1:

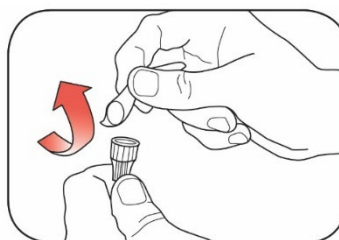
- Pull the Pen Cap straight off.
 - **Do not** remove the KwikPen Label.
- Wipe the Rubber Seal with an alcohol swab.

ONSWIK should look clear and colorless to yellow.
Do not use if it is cloudy, discolored, or has particles or clumps in it.



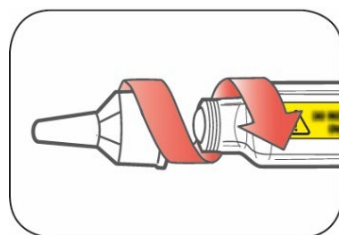
Step 2:

- Select a new Needle.
- Pull off the Paper Tab from the Outer Needle Shield.



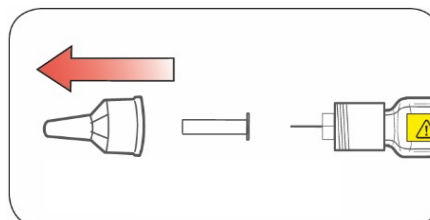
Step 3:

- Push the capped Needle straight onto the Pen and twist the Needle clockwise (to the right) until it is tight.



Step 4:

- Pull off the Outer Needle Shield. **Do not** throw it away.
- Pull off the Inner Needle Shield and throw it away.



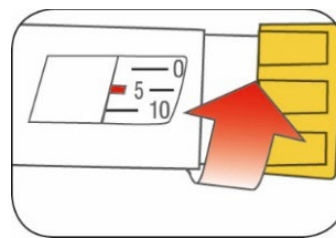
Priming your Pen

Prime before each injection.

- Priming your Pen means removing the air from the Needle and Cartridge that may collect during normal use and ensures that the Pen is working correctly.
- If you **do not** prime before each injection, you may get too little insulin.

Step 5:

- To prime your pen, turn the Dose Knob to **select 5 units**.



Step 6:

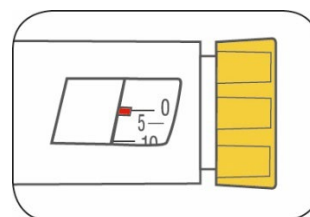
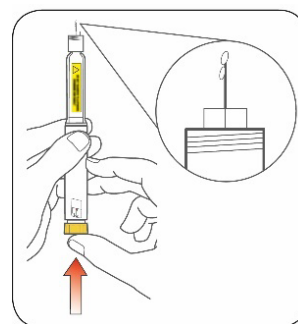
- Hold your Pen with the Needle pointing up. Tap the Cartridge Holder gently to collect air bubbles at the top.



Step 7:

- Continue holding your Pen with the Needle pointing up. Push the Dose Knob in until it stops, and “0” is seen in the Dose Window. Hold the Dose Knob in and **count to 5 slowly**.
You should see insulin at the tip of the Needle.
 - If you **do not** see insulin, repeat priming steps 5 to 7, no more than 8 times.
 - If you **still do not** see insulin, change the Needle and repeat priming steps 5 to 7.

Small air bubbles are normal and will not affect your dose.



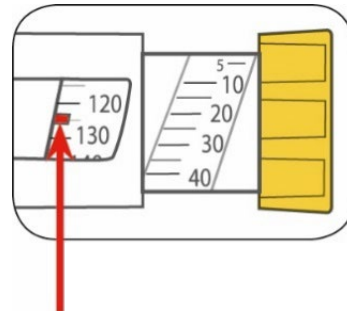
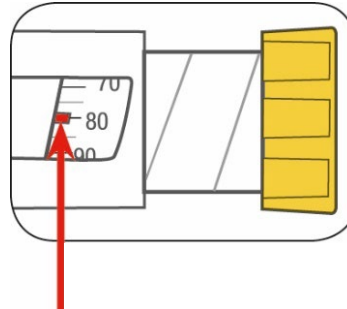
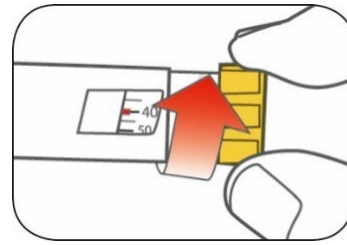
Selecting your dose

This Pen has been made to deliver the dose **in insulin units** that is shown in the Dose Window. Ask your healthcare provider what your dose should be for this Pen.

- You can give from 5 units to 400 units in a single injection.
- If your dose is more than 400 units, you will need to give more than 1 injection.
 - If you need help with dividing up your dose the right way, ask your healthcare provider.
 - Use a new Needle for each injection and repeat the priming step.

Step 8:

- Turn the Dose Knob to select the number of units you need to inject. The Dose Indicator should line up with your dose.
 - The Dose Knob clicks as you turn it. Each click of the Dose Knob dials **5 insulin units** at a time.
 - **Do not dial your dose by counting the clicks. You may dial the wrong dose. This may lead to you getting too much insulin or not enough insulin.**
 - The dose can be corrected by turning the Dose Knob in either direction until the correct dose lines up with the Dose Indicator.
 - The **even** numbers (for example, 80) are printed on the dial.
 - The **odd** numbers (for example, 125) are shown as lines between the even numbers.
- **Always check the number in the Dose Window to make sure you have dialed the correct dose.**



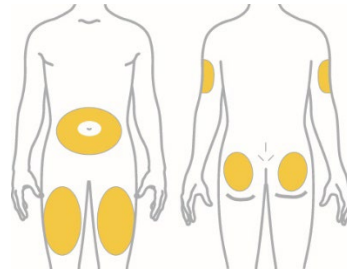
-
- The Pen will not let you dial more than the number of units left in the Pen.
 - If your dose is more than the number of units left in the Pen, you may either:
 - inject the amount left in your Pen and then use a new Pen to give the rest of your dose,
 - or**
 - get a new Pen and inject your full dose.
 - It is normal to see a small amount of insulin left in the Pen that you cannot inject. **Do not transfer the insulin to a syringe. Severe overdose can happen.**

Giving your injection

- Inject your insulin as your healthcare provider has shown you.
- Change (rotate) your injection sites within the area you choose for each injection to reduce your risk of getting pits in skin or thickened skin (lipodystrophy) and skin with lumps (localized cutaneous amyloidosis) at the injection sites.
 - **Do not** inject where the skin has pits, is thickened, or has lumps.
 - **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- **Do not** try to change your dose while injecting.

Step 9:

- Choose your injection site.
ONSWIK is injected under the skin (subcutaneously) of your stomach area, buttocks, thigh, or the back of the upper arms.
- Wipe your skin with an alcohol swab and let your skin dry before you inject your dose.

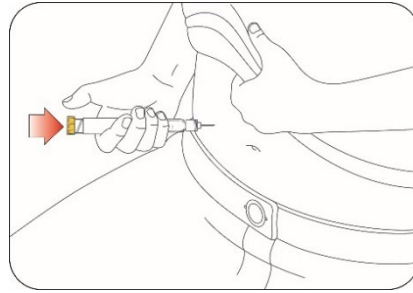


Step 10:

- Insert the Needle into your skin.
- Push the Dose Knob all the way in.
- Continue to hold the Dose Knob all the way in and **slowly count to 5** before removing the Needle.

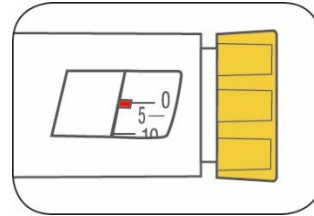


Do not try to inject your insulin by turning the Dose Knob. You will **not** receive your insulin by turning the Dose Knob.



Step 11:

- Pull the Needle out of your skin.
 - A drop of insulin at the Needle tip is normal. It will not affect your dose.
- Check the number in the Dose Window.
 - If you see “0” in the Dose Window, you have received the full amount you dialed.
 - If you do not see “0” in the Dose Window, **do not** redial. Insert the Needle into your skin and finish your injection.
 - If you **still** do not think you received the full amount you dialed for your injection, **do not start over or repeat your injection.** Monitor your blood sugar (glucose) as instructed by your healthcare provider.



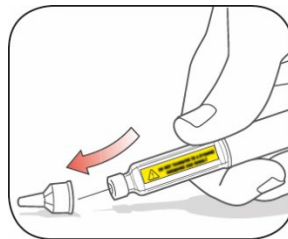
The Plunger only moves a little with each injection, and you may not notice that it moves.

If you see blood after you take the Needle out of your skin, press the injection site lightly with a piece of gauze or an alcohol swab. **Do not** rub the area.

After your injection

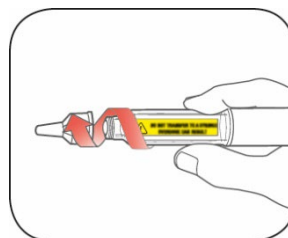
Step 12:

- Carefully replace the Outer Needle Shield.



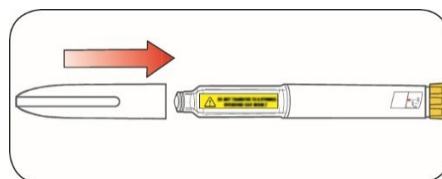
Step 13:

- Unscrew the capped Needle and throw it away (see **Throwing away (disposing of) Pens and Needles** section).
- Do not** store the Pen with the Needle attached to prevent leaking, blocking the Needle, and air from entering the Pen.



Step 14:

- Replace the Pen Cap by lining up the Cap Clip with the Dose Indicator and pushing straight on.



Throwing away (disposing of) Pens and Needles

- Throw away your used Needles in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) loose Needles in your household trash.
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- Do not** throw away (dispose of) your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.
- The used Pen may be thrown away (discarded) in your household trash after you have removed the needle.

What you should know if you are switching to ONSWIK KwikPen

Ask your healthcare provider what your dose should be for your Pen in **insulin units**. Always follow your healthcare provider's instructions for dosing.

If you are:	It is important to know:
Switching from another type of insulin device or pen.	This ONSWIK KwikPen is different from other pens. It dials 5 insulin units with each click of the Dose Knob. Do not select your dose by counting clicks. You may get too much insulin or you may not get enough insulin.

General information about the safe and effective use of your Pen

- **Keep your Pen and Needles out of the sight and reach of children.**
- **Do not** use your Pen if any part looks broken or damaged. Always have an extra Pen in case yours is lost or damaged.

Troubleshooting

- If you cannot remove the Pen Cap, gently twist the cap back and forth, and then pull the cap straight off.
- If it is hard to push the Dose Knob:
 - Pushing the Dose Knob more slowly will make it easier to inject.
 - Your Needle may be blocked. Put on a new Needle and prime the Pen.
 - You may have dust, food, or liquid inside the Pen. Throw the Pen away and get a new Pen.

If you have any questions or problems with your ONSWIK KwikPen, contact Lilly at 1-800-LillyRx (1-800-545-5979) or call your healthcare provider for help. For more information on ONSWIK KwikPen and insulin, go to www.ONSWIK.lilly.com.



Scan this code to launch
www.ONSWIK.lilly.com

Manufactured by
Eli Lilly and Company
Indianapolis, IN 46285, USA
U.S. License Number: 1891

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Issued: September 2026

ONSWIK KwikPen meets the current dose accuracy and functional requirements of ISO 11608-1.

A3.0-ONS-KP-0000-IFU-U500-YYYYMMDD

INSTRUCTIONS FOR USE

ONSWIK™ KwikPen® [ON-swihk KWIHK-pehn]

(insulin efsitora alfa-gobe)

injection, for subcutaneous use

3 mL single-patient-use pen (1,000 units/mL, U-1,000)



Important:

- **ONSWIK KwikPen is used 1 time each week (once weekly).**
- This ONSWIK KwikPen® (Pen) works differently from other pens. It dials 10 insulin units with each click. **Do not count clicks of the dose knob to select your dose. You may get too much insulin or you may not get enough insulin.**
- **Do not transfer ONSWIK insulin from your Pen into a syringe. A severe overdose can happen, causing very low blood sugar, which may put your life in danger.**
- **Know your dose of ONSWIK insulin.** The Pen delivers your dose in **insulin units**. Insulin units may **not be the same** as syringe markings. **Ask your healthcare provider what your dose should be for your Pen.**



**DO NOT TRANSFER TO A SYRINGE
SEVERE OVERDOSE CAN RESULT**

Read this Instructions for Use before you start injecting ONSWIK KwikPen and each time you get another Pen. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

ONSWIK KwikPen ("Pen") is a disposable (can be thrown away) single-patient-use prefilled pen containing 3,000 units of ONSWIK. You can give yourself more than 1 dose from the Pen. Each turn (click) of the Dose Knob dials 10 units of insulin. You can give from 10 units to 800 units in a single injection. **If your dose is more than 800 units, you will need to give yourself more than 1 injection.**

The Plunger only moves a little with each injection, and you may not notice that it moves. The Plunger will only reach the end of the cartridge when you have used all 3,000 units in the Pen. When the Pen is empty, throw away the entire Pen and get a new Pen (see **Throwing away (disposing of) Pens and Needles** section at the end of this Instructions for Use).

ONSWIK KwikPen is used 1 time a week. You may want to mark your calendar to remind yourself when to take your next dose.

Inject ONSWIK only with your Pen. Do not transfer insulin from your Pen to a syringe. A severe overdose can happen, causing very low blood sugar, which may put your life in danger.

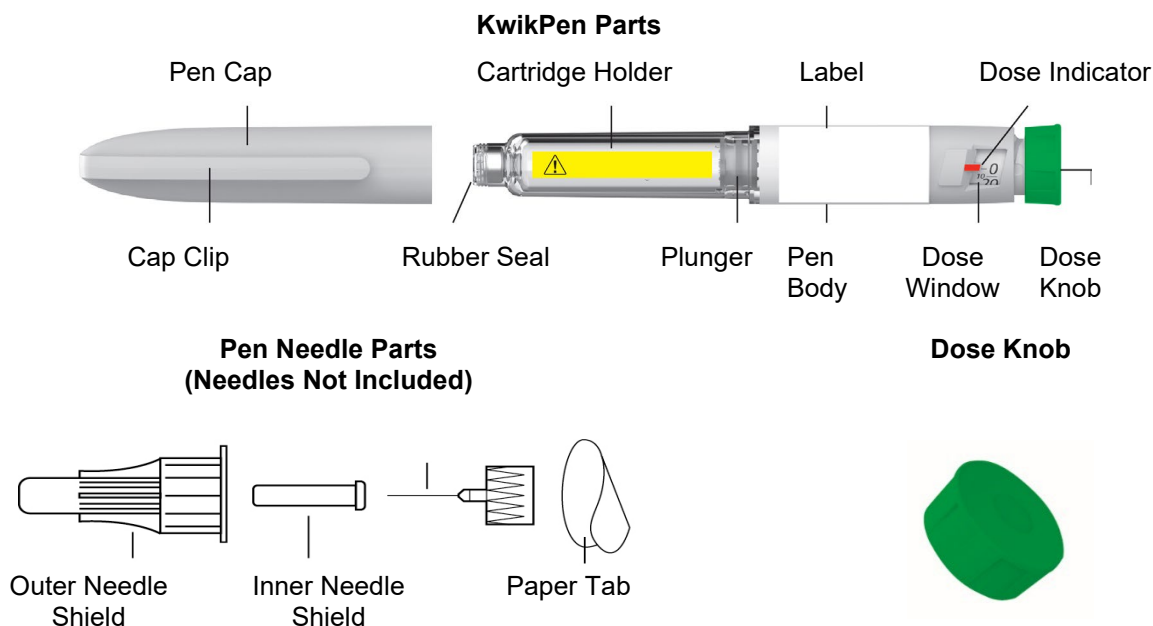
People who are blind or have vision problems should not use the Pen without help from a person trained to use the Pen.

Do not share your ONSWIK KwikPen with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

Storing your Pen

Keep your Pen refrigerated.

- Store the Pen you are currently using in the refrigerator at 36°F to 46°F (2°C to 8°C) at all times.
- If you are not able to refrigerate the Pen, the Pen can be stored at room temperature up to 86°F (30°C) for up to a total of 14 days.
 - **Do not** freeze ONSWIK KwikPen. **Do not** use if it has been frozen.
- Keep away from heat and light.
- If the Pen has been stored in the refrigerator, **throw away the Pen you are using after 112 days (16 weeks), even if it still has ONSWIK in it.**
 - If the Pen has been at room temperature for over 14 days, **throw away** the Pen.
- Do not use your Pen past the expiration date printed on the Label.



How to recognize your ONSWIK KwikPen

- Pen color: Light Gray
- Dose Knob: Green
- Label: ONSWIK KwikPen 1,000 units per mL

1,000 units
mL

Supplies needed to give your injection

- ONSWIK KwikPen
- KwikPen compatible Needle (29 to 32 gauge needle recommended)
- 1 alcohol swab
- 1 cotton ball or piece of gauze
- 1 FDA-cleared sharps disposal container

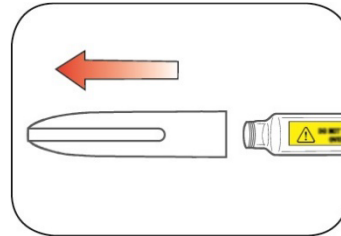
Preparing your Pen

- Wash your hands with soap and water.
- Check the Pen to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- **Do not** use your Pen past the expiration date printed on the Label or for more than 112 days (16 weeks) after you first start using the Pen.
- **Always use a new Needle for each injection to help prevent infections and blocked Needles. Do not reuse or share your needles with other people. You may give other people a serious infection or get a serious infection from them.**

Step 1:

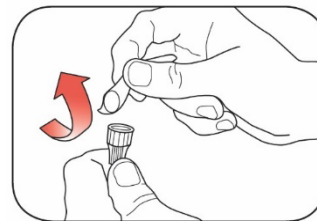
- Pull the Pen Cap straight off.
 - **Do not** remove the KwikPen Label.
- Wipe the Rubber Seal with an alcohol swab.

ONSWIK should look clear and colorless to yellow.
Do not use if it is cloudy, discolored, or has particles or clumps in it.



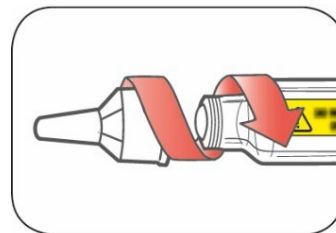
Step 2:

- Select a new Needle.
- Pull off the Paper Tab from the Outer Needle Shield.



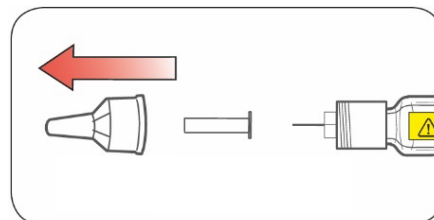
Step 3:

- Push the capped Needle straight onto the Pen and twist the Needle clockwise (to the right) until it is tight.



Step 4:

- Pull off the Outer Needle Shield. **Do not** throw it away.
- Pull off the Inner Needle Shield and throw it away.



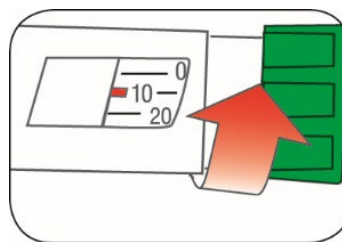
Priming your Pen

Prime before each injection.

- Priming your Pen means removing the air from the Needle and Cartridge that may collect during normal use and ensures that the Pen is working correctly.
- If you **do not** prime before each injection, you may get too little insulin.

Step 5:

- To prime your pen, turn the Dose Knob to **select 10 units**.



Step 6:

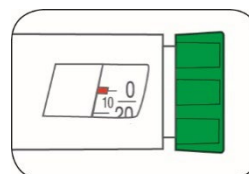
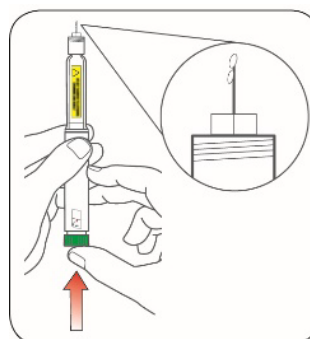
- Hold your Pen with the Needle pointing up. Tap the Cartridge Holder gently to collect air bubbles at the top.



Step 7:

- Continue holding your Pen with the Needle pointing up. Push the Dose Knob in until it stops, and “0” is seen in the Dose Window. Hold the Dose Knob in and **count to 5 slowly**.
You should see insulin at the tip of the Needle.
 - If you **do not** see insulin, repeat priming steps 5 to 7, no more than 8 times.
 - If you **still do not** see insulin, change the Needle and repeat priming steps 5 to 7.

Small air bubbles are normal and will not affect your dose.



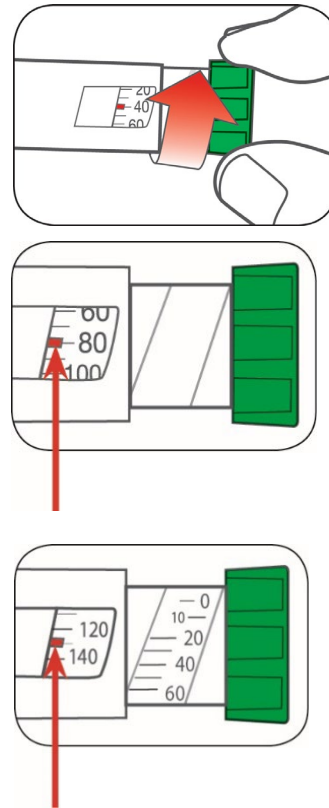
Selecting your dose

This Pen has been made to deliver the dose **in insulin units** that is shown in the Dose Window. Ask your healthcare provider what your dose should be for this Pen.

- You can give from 10 units to 800 units in a single injection.
- If your dose is more than 800 units, you will need to give more than 1 injection.
 - If you need help with dividing up your dose the right way, ask your healthcare provider.
 - Use a new Needle for each injection and repeat the priming step.

Step 8:

- Turn the Dose Knob to select the number of units you need to inject. The Dose Indicator should line up with your dose.
 - The Dose Knob clicks as you turn it. Each click of the Dose Knob dials **10 insulin units** at a time.
 - **Do not dial your dose by counting the clicks. You may dial the wrong dose. This may lead to you getting too much insulin or not enough insulin.**
 - The dose can be corrected by turning the Dose Knob in either direction until the correct dose lines up with the Dose Indicator.
- **Always check the number in the Dose Window to make sure you have dialed the correct dose.**



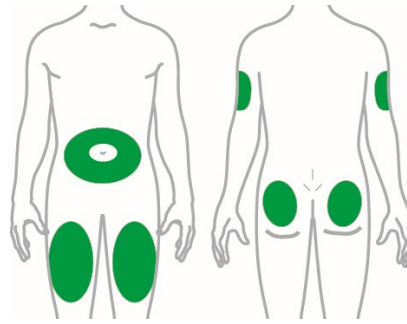
-
- The Pen will not let you dial more than the number of units left in the Pen.
 - If your dose is more than the number of units left in the Pen, you may either:
 - inject the amount left in your Pen and then use a new Pen to give the rest of your dose,
 - or**
 - get a new Pen and inject your full dose.
 - It is normal to see a small amount of insulin left in the Pen that you cannot inject. **Do not transfer the insulin to a syringe. Severe overdose can happen.**

Giving your injection

- Inject your insulin as your healthcare provider has shown you.
- Change (rotate) your injection sites within the area you choose for each injection to reduce your risk of getting pits in the skin or thickened skin (lipodystrophy) and skin with lumps (localized cutaneous amyloidosis) at the injection sites.
 - **Do not** inject where the skin has pits, is thickened, or has lumps.
 - **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- **Do not** try to change your dose while injecting.

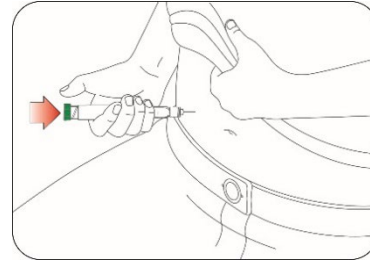
Step 9:

- Choose your injection site.
ONSWIK is injected under the skin (subcutaneously) of your stomach area, buttocks, thigh, or the back of the upper arms.
- Wipe your skin with an alcohol swab and let your skin dry before you inject your dose.



Step 10:

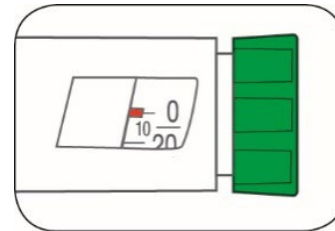
- Insert the Needle into your skin.
- Push the Dose Knob all the way in.
- Continue to hold the Dose Knob all the way in and **slowly count to 5** before removing the Needle.



Do not try to inject your insulin by turning the Dose Knob. You will **not** receive your insulin by turning the Dose Knob.

Step 11:

- Pull the Needle out of your skin.
 - A drop of insulin at the Needle tip is normal. It will not affect your dose.
- Check the number in the Dose Window.
 - If you see “0” in the Dose Window, you have received the full amount you dialed.
 - If you do not see “0” in the Dose Window, **do not** redial. Insert the Needle into your skin and finish your injection.
 - If you **still** do not think you received the full amount you dialed for your injection, **do not start over or repeat your injection**. Monitor your blood sugar (glucose) as instructed by your healthcare provider.



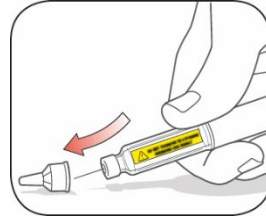
The Plunger only moves a little with each injection, and you may not notice that it moves.

If you see blood after you take the Needle out of your skin, press the injection site lightly with a piece of gauze or an alcohol swab. **Do not** rub the area.

After your injection

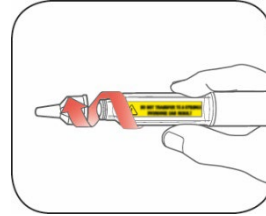
Step 12:

- Carefully replace the Outer Needle Shield.



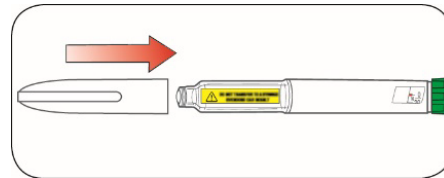
Step 13:

- Unscrew the capped Needle and throw it away (see **Throwing away (disposing of) Pens and Needles** section).
- Do not** store the Pen with the Needle attached to prevent leaking, blocking the Needle, and air from entering the Pen.



Step 14:

- Replace the Pen Cap by lining up the Cap Clip with the Dose Indicator and pushing straight on.



Throwing away (disposing of) Pens and Needles

- Throw away your used Needles in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) loose Needles in your household trash.
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
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- The used Pen may be thrown away (discarded) in your household trash after you have removed the needle.

What you should know if you are switching to ONSWIK KwikPen

Ask your healthcare provider what your dose should be for your Pen in **insulin units**. Always follow your healthcare provider's instructions for dosing.

If you are:	It is important to know:
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Troubleshooting

- If you cannot remove the Pen Cap, gently twist the cap back and forth, and then pull the cap straight off.
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 - You may have dust, food, or liquid inside the Pen. Throw the Pen away and get a new Pen.

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