

FDA-Approved Insulin Products

RAPID-ACTING INSULINS

Rapid-acting insulins have an onset of action within 15 minutes, peak effect at approximately 1 to 2 hours, and duration of 3 to 5 hours. They are typically administered at or just before meals.

Admelog* (insulin lispro)

Application: BLA209196 | **Manufacturer:** Sanofi | **Customer Service:** 1-800-633-1610 |
Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials and SoloStar pens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 28 days.

In-use SoloStar pen (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin lispro product (e.g., Humalog) to Admelog, use the same unit dose (unit-for-unit substitution).

When switching from other insulin classes to Admelog, dosage adjustment may be needed.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

3. Insulin Pump Use Instructions:

Admelog U-100 is approved for use in compatible CSII pumps.

Change the insulin reservoir and infusion set at least every 7 days or per the pump manufacturer instructions, whichever is sooner.

Do not dilute or mix Admelog with any other insulin when used in a pump.

Discard insulin exposed to temperatures exceeding 98.6 degrees F.

Afrezza (insulin human inhalation powder)

Application: BLA022472 | **Manufacturer:** MannKind Corporation | **Customer Service:** 1-844-323-7399 | **Label:** [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened foil packages: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date.

Unsealed blister cards and strips stored in the refrigerator: Use within 1 month.

Foil packages, blister cards, or strips stored at room temperature (approximately 77 degrees F; excursions 59 degrees F to 86 degrees F): Use within 10 days.

Opened strips stored at room temperature: Use within 3 days.

Do not return blister cards or strips to the refrigerator after storage at room temperature.

Before use, leave cartridges and inhaler at room temperature for at least 10 minutes.

Replace the inhaler every 15 days from first use.

Do not allow cartridges or the inhaler to get wet. Store the inhaler with the mouthpiece cover on in a clean, dry place.

2. Switching Instructions:

Afrezza is a rapid-acting inhaled insulin for mealtime use. Administer at the beginning of each meal.

When switching from injected mealtime insulin to Afrezza, use the following conversion: up to 3 units converts to 4 units of Afrezza; 4 to 5 units converts to 8 units; 6 to 7 units converts to 12 units; 8 or more units converts to 16 units.

Patients with type 1 diabetes must continue basal insulin when using Afrezza.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

3. Insulin Pump Use Instructions:

Not applicable. Afrezza is an inhaled insulin administered via the Afrezza Inhaler by oral inhalation only. It cannot be used with any injection device, pump, or syringe.

Apidra (insulin glulisine)

Application: BLA021629 | **Manufacturer:** Sanofi | **Customer Service:** 1-800-633-1610 |

Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials and SoloStar pens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): May be stored refrigerated or at room temperature at or below 77 degrees F for up to 28 days.

In-use SoloStar pen (opened): Store at room temperature at or below 77 degrees F for up to 28 days. Do not refrigerate after first use.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to Apidra, dosage adjustment may be needed.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

Apidra may be mixed with NPH insulin for subcutaneous injection only. Draw Apidra into the syringe first and inject immediately after mixing. Do not mix for pump use.

3. Insulin Pump Use Instructions:

Apidra is approved for use in compatible CSII pumps.

Change the insulin reservoir and infusion set at least every 48 hours or per the pump manufacturer instructions, whichever is sooner.

Do not dilute or mix Apidra with any other insulin when used in a pump.

Discard insulin exposed to temperatures exceeding 98.6 degrees F.

Fiasp (insulin aspart)

Application: BLA208751 | Manufacturer: Novo Nordisk | Customer Service: 1-800-727-6500 |

Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials, FlexTouch pens, PenFill cartridges, and PumpCart: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): Store refrigerated or at room temperature below 86 degrees F for up to 28 days.

In-use FlexTouch pen (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 28 days.

In-use PenFill cartridge (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

In-use PumpCart (opened): Store at room temperature below 86 degrees F. Discard after 4 days in the pump or 18 days total at room temperature, whichever comes first. Do not refrigerate after first use.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When converting from another mealtime insulin to Fiasp, the initial change can be made on a unit-to-unit basis.

Closely monitor blood glucose when converting insulins used in insulin pumps, as individualization of pump parameters may be necessary.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

Do not mix Fiasp with any other insulin products.

3. Insulin Pump Use Instructions:

Fiasp is approved for use in compatible CSII pumps (vial or dedicated PumpCart formulation).

Change the insulin reservoir and infusion set at least every 6 days (vial) or every 4 days (PumpCart), or per the pump manufacturer instructions, whichever is sooner.

Do not dilute or mix Fiasp with any other insulin when used in a pump.

Discard insulin exposed to temperatures exceeding 98.6 degrees F.

Garzulys* (insulin aspart-fsan)

Application: BLA (approved July 2026) | Manufacturer: Meitheal Pharmaceuticals | Customer Service: 1-844-824-8426 | Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Garzulys is a biosimilar to NovoLog (insulin aspart). Full storage details should be verified against the current FDA-approved prescribing information upon availability.

General guidance: Store unopened product in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

2. Switching Instructions:

As a biosimilar to NovoLog, switching guidance is expected to follow insulin aspart labeling conventions. Verify against current approved labeling.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

3. Insulin Pump Use Instructions:

Pump compatibility should be verified against current FDA-approved Garzulys labeling upon availability. Change the Garzulys in the reservoir at least every 7 days or according to the pump user manual, whichever is shorter.

Humalog (insulin lispro)

Application: BLA020563 / BLA205747 | Manufacturer: Lilly | Customer Service: 1-800-545-5979 | Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials, cartridges, KwikPens, Junior KwikPens, and Tempo Pens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 28 days.

In-use pens and cartridges (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

Humalog U-200 KwikPen: Same 28-day room-temperature limit; do not refrigerate after first use.

Diluted Humalog U-100 (subcutaneous use only): Stable for 28 days refrigerated at 41 degrees F or 14 days at room temperature below 86 degrees F.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to Humalog, a different dosage may be needed.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

Humalog U-100 may be mixed with NPH insulin for subcutaneous injection only. Draw Humalog first and inject immediately after mixing. Do not mix for pump use.

Do not mix Humalog U-200 with any other insulin.

3. Insulin Pump Use Instructions:

Humalog U-100 is approved for use in compatible CSII pumps.

Humalog U-200 must NOT be used in an insulin pump.

Change the insulin reservoir and infusion set at least every 7 days or per the pump manufacturer instructions, whichever is sooner.

Do not dilute or mix Humalog in the pump.

Discard insulin exposed to temperatures exceeding 98.6 degrees F.

Kirsty* (insulin aspart-xjhz)

Application: BLA761188 | **Manufacturer:** Biocon Biologics | **Customer Service:** 1-833-986-1468 |

Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials and prefilled pens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): Store refrigerated or at room temperature below 86 degrees F for up to 28 days. If used in a pump, discard after 19 days.

In-use prefilled pen (opened): Store at room temperature below 86 degrees F for up to 28 days.

Do not refrigerate after first use.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to Kirsty, a different dosage may be needed.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

Kirsty may be mixed with NPH insulin for subcutaneous injection only. Withdraw Kirsty first and inject immediately after mixing. Do not mix for pump use.

3. Insulin Pump Use Instructions:

Kirsty is approved for use in CSII pumps labeled for use with Kirsty or NovoLog (insulin aspart).

Change the insulin reservoir and infusion set at least every 7 days or per the pump manufacturer instructions, whichever is sooner.

Do not dilute or mix Kirsty with any other insulin when used in a pump.

Discard insulin exposed to temperatures exceeding 98.6 degrees F.

Lyumjev (insulin lispro-aabc)

Application: BLA761109 | **Manufacturer:** Lilly | **Customer Service:** 1-800-545-5979 | **Label:**

[DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials and pens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 28 days.

In-use pens (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When converting from another mealtime insulin to Lyumjev, the change can be made on a unit-to-unit basis.

Dosage adjustments may still be needed. Make all regimen changes under close medical supervision with increased blood glucose monitoring.

Do not mix Lyumjev with any other insulin products.

3. Insulin Pump Use Instructions:

Lyumjev U-100 is approved for use in compatible CSII pumps.

Lyumjev U-200 must NOT be used in an insulin pump.

Change the insulin reservoir and infusion set at least every 9 days or per the pump manufacturer instructions, whichever is sooner.

Do not dilute or mix Lyumjev in the pump.

Discard insulin exposed to temperatures exceeding 98.6 degrees F.

Merilog* (insulin aspart-szjj)

Application: BLA761325 | Manufacturer: Sanofi | Customer Service: 1-800-633-1610 | Label:
[DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials and SoloStar pens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 28 days.

In-use SoloStar pen (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to Merilog, a different dosage may be needed.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

Do not mix Merilog with any other insulin products.

3. Insulin Pump Use Instructions:

Not approved for pump use. Merilog is indicated for subcutaneous injection only. Do not use in a CSII pump.

NovoLog (insulin aspart)

Application: BLA020986 | **Manufacturer:** Novo Nordisk | **Customer Service:** 1-800-727-6500 |

Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials, PenFill cartridges, and FlexPens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 28 days.

In-use FlexPen (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to NovoLog, a different dosage may be needed.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

NovoLog may be mixed with NPH insulin for subcutaneous injection only. Withdraw NovoLog first and inject immediately after mixing. Do not mix for pump use.

3. Insulin Pump Use Instructions:

NovoLog is approved for use in compatible CSII pumps.

Change the insulin reservoir and infusion set at least every 7 days or per the pump manufacturer instructions, whichever is sooner.

Do not dilute or mix NovoLog with any other insulin when used in a pump.

Discard insulin exposed to temperatures exceeding 98.6 degrees F.

SHORT-ACTING INSULINS (REGULAR HUMAN INSULIN)

Regular human insulins have an onset of action within 30 to 60 minutes, peak effect at 2 to 4 hours, and duration of 5 to 8 hours. They are typically administered 30 minutes before meals.

Humulin R U-100 (insulin human)

Application: BLA018780 | **Manufacturer:** Lilly | **Customer Service:** 1-800-545-5979 | **Label:**

[DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 28 days.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to Humulin R, dosage adjustment may be needed. Make all regimen changes under close medical supervision with increased blood glucose monitoring. Humulin R may be mixed with Humulin N (NPH). Draw Humulin R into the syringe first and inject immediately after mixing.

3. Insulin Pump Use Instructions:

Not approved for routine pump use. Humulin R U-100 is a regular human insulin and is generally not recommended for CSII pump therapy. Rapid-acting insulin analogs are preferred for pump use.

Humulin R U-500 (insulin human 500 units/mL)

Application: BLA018780 | **Manufacturer:** Lilly | **Customer Service:** 1-800-545-5979 | **Label:** [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened 20 mL vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. At room temperature below 86 degrees F, use within 40 days total (combined unopened and in-use time).

In-use 20 mL vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 40 days.

Unopened 3 mL KwikPen: Store in a refrigerator until the expiration date. At room temperature below 86 degrees F, use within 28 days total.

In-use 3 mL KwikPen (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

Do not freeze. Protect from direct heat and light. Discard if frozen.

CAUTION: Humulin R U-500 is 5 times more concentrated than U-100 insulin. Use only a U-500 syringe with the vial. Do not transfer from the KwikPen into any syringe.

2. Switching Instructions:

Humulin R U-500 is indicated only for patients requiring more than 200 units of insulin per day. When switching from the vial to the KwikPen, confirm the correct unit dose with the healthcare provider. The KwikPen dials 5 insulin units per click; do not select dose by counting clicks.

Do not perform dose conversion when using the KwikPen or U-500 syringe. The dose window and syringe markings display units directly.

Do not dilute or mix Humulin R U-500 with any other insulin products or solutions.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

3. Insulin Pump Use Instructions:

Not approved for pump use. Humulin R U-500 must not be used in an insulin infusion pump.

Novolin R (human insulin)

Application: BLA019938 | Manufacturer: Novo Nordisk | Customer Service: 1-800-727-6500 |
Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date.
Do not freeze.

In-use vials (opened): Consult current prescribing information for specific in-use storage duration and temperature limits.

Protect from direct heat and light. Discard if frozen.

Unopened 10 mL vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. At room temperature below 77 degrees F, use within 42 days.

In-use 10 mL vials (opened): May be stored at room temperature below 77 degrees F for up to 42 days.

Unopened 3 mL FlexPen: Store in a refrigerator until the expiration date. At room temperature below 86 degrees F, use within 28 days total.

In-use 3 mL FlexPen (opened): Store at room temperature below 86 degrees F for up to 28 days.
Do not refrigerate after first use.

2. Switching Instructions:

When switching from another insulin to Novolin R, dosage adjustment may be needed.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

Novolin R may be mixed with Novolin N. Draw Novolin R into the syringe first and inject immediately after mixing.

Novolin R given by subcutaneous injection should generally be used in regimens that include an intermediate- or long-acting insulin.

3. Insulin Pump Use Instructions:

Not recommended for pump use. The Novolin R prescribing information specifically states that use in insulin pumps is not recommended due to the risk of precipitation.

INTERMEDIATE-ACTING INSULINS

Intermediate-acting insulins (NPH) have an onset of action within 1 to 3 hours, peak effect at 4 to 12 hours, and duration of 12 to 18 hours.

Humulin N (insulin isophane human (NPH))

Application: BLA018781 | Manufacturer: Lilly | Customer Service: 1-800-545-5979 | Label:
[DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened 10 mL vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. At room temperature below 86 degrees F, use within 31 days total (combined unopened and in-use time).

In-use 10 mL vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 31 days.

Unopened 3 mL KwikPen: Store in a refrigerator until the expiration date. At room temperature below 86 degrees F, use within 14 days total.

In-use 3 mL KwikPen (opened): Store at room temperature below 86 degrees F for up to 14 days. Do not refrigerate after first use.

Do not freeze. Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to Humulin N, dosage adjustment may be needed.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

Humulin N may be mixed with Humulin R or Humalog for subcutaneous injection. Draw the rapid- or short-acting insulin into the syringe first and inject immediately after mixing.

3. Insulin Pump Use Instructions:

Not approved for pump use. Humulin N must not be used in an insulin infusion pump.

Novolin N (human insulin isophane (NPH))

Application: BLA019959 | **Manufacturer:** Novo Nordisk | **Customer Service:** 1-800-727-6500 |

Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

Unopened 10 mL vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. At room temperature below 77 degrees F, use within 42 days.

In-use 10 mL vials (opened): May be stored at room temperature below 77 degrees F for up to 42 days.

Unopened 3 mL FlexPen: Store in a refrigerator until the expiration date. At room temperature below 86 degrees F, use within 14 days total.

In-use 3 mL FlexPen (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

Do not freeze. Protect from direct heat and light. Discard if frozen.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to Novolin N, dosage adjustment may be needed.

In patients with type 1 diabetes, Novolin N should generally be used in regimens that include a short-acting insulin.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

Novolin N may be mixed with Novolin R. Draw Novolin R into the syringe first, followed by Novolin N, and inject immediately after mixing.

3. Insulin Pump Use Instructions:

Not approved for pump use. Novolin N must not be used in an insulin infusion pump.

LONG-ACTING INSULINS

Long-acting insulins provide basal insulin coverage for approximately 20 to 24 hours with a relatively flat pharmacokinetic profile and no pronounced peak. They are typically administered once daily.

Basaglar* (insulin glargine)

Application: BLA205692 | **Manufacturer:** Lilly | **Customer Service:** 1-800-545-5979 | **Label:** [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened KwikPens and Tempo Pens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. At room temperature below 86 degrees F, use within 28 days.

In-use pens (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

Do not freeze. Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin glargine 100 units/mL product to Basaglar, use the same unit dose.

When switching from insulin glargine 300 units/mL (e.g., Toujeo) to Basaglar, start at 80 percent of the glargine 300 units/mL dose.

When switching from once-daily NPH insulin, start at the same unit dose as the NPH dose being discontinued.

When switching from twice-daily NPH insulin, start at 80 percent of the total daily NPH dose.

Monitor blood glucose closely when converting to Basaglar and during the initial weeks of therapy.

Do not dilute or mix Basaglar with any other insulin or solution.

3. Insulin Pump Use Instructions:

Not approved for pump use. Basaglar must not be administered intravenously or used in an insulin infusion pump.

Langlara* (insulin glargine-aldy)

Application: BLA (approved April 2026) | **Manufacturer:** Lanexa Biologics, LLC | **Customer Service:** 1-800-610-5709 | **Label:** [DailyMed Prescribing Information](#)

1. Storage Instructions:

Langlara is a biosimilar and interchangeable with Lantus (insulin glargine). Full storage details should be verified against the current FDA-approved prescribing information.

General guidance: Store unopened product in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use pens (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

2. Switching Instructions:

As a biosimilar interchangeable with Lantus, switching guidance is expected to follow insulin glargine 100 units/mL labeling conventions. Verify against current approved labeling.

When switching from insulin glargine 300 units/mL (e.g., Toujeo) to Langlara, start at 80 percent of the glargine 300 units/mL dose.

When switching from once-daily NPH insulin, start at the same unit dose as the NPH dose being discontinued.

When switching from twice-daily NPH insulin, start at 80 percent of the total daily NPH dose.

Monitor blood glucose closely during any insulin regimen change.

3. Insulin Pump Use Instructions:

Not approved for pump use. Verify against current FDA-approved Langlara labeling.

Lantus (insulin glargine)

Application: BLA021081 | **Manufacturer:** Sanofi | **Customer Service:** 1-800-633-1610 | **Label:** [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials and SoloStar pens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 28 days.

In-use SoloStar pen (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

Protect from direct heat and light. Discard if frozen or overheated.

2. Switching Instructions:

When switching from Toujeo (insulin glargine 300 units/mL) to Lantus (100 units/mL), start Lantus at 80 percent of the Toujeo dose.

When switching from once-daily NPH insulin, start at the same unit dose as the NPH dose being discontinued.

When switching from twice-daily NPH insulin, start at 80 percent of the total daily NPH dose.

Monitor blood glucose closely when converting to Lantus and during the initial weeks of therapy.

Do not dilute or mix Lantus with any other insulin or solution.

3. Insulin Pump Use Instructions:

Not approved for pump use. Lantus must not be administered intravenously or used in an insulin infusion pump.

Rezvoglar* (insulin glargine-aglr)

Application: BLA761215 | **Manufacturer:** Lilly | **Customer Service:** 1-800-545-5979 | **Label:** [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened KwikPens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use KwikPen (opened): Store at room temperature below 86 degrees F. The total combined time at room temperature (unopened plus in-use) must not exceed 28 days. Do not refrigerate after first use.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from insulin glargine 300 units/mL to Rezvoglar (100 units/mL), start at 80 percent of the glargine 300 units/mL dose.

When switching from once-daily NPH insulin, start at the same unit dose as the NPH dose being discontinued.

When switching from twice-daily NPH insulin, start at 80 percent of the total daily NPH dose.

Monitor blood glucose closely when converting to Rezvoglar and during the initial weeks of therapy.

Do not dilute or mix Rezvoglar with any other insulin or solution.

3. Insulin Pump Use Instructions:

Not approved for pump use. Rezvoglar must not be administered intravenously or used in an insulin infusion pump.

Semglee* (insulin glargine-yfgn)

Application: BLA761201 | **Manufacturer:** Biocon Biologics / Viatris | **Customer Service:** 1-833-986-1468 | **Label:** [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials and pens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 28 days.

In-use prefilled pen (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from insulin glargine 300 units/mL to Semglee (100 units/mL), start at 80 percent of the glargine 300 units/mL dose.

When switching from once-daily NPH insulin, start at the same unit dose as the NPH dose being discontinued.

When switching from twice-daily NPH insulin, start at 80 percent of the total daily NPH dose. Monitor blood glucose closely when converting to Semglee and during the initial weeks of therapy.

Do not dilute or mix Semglee with any other insulin or solution.

3. Insulin Pump Use Instructions:

Not approved for pump use. Semglee must not be administered intravenously or used in an insulin infusion pump.

Toujeo (insulin glargine 300 units/mL)

Application: BLA206538 | **Manufacturer:** Sanofi | **Customer Service:** 1-800-633-1610 | **Label:** [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened SoloStar and Max SoloStar pens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use pens (opened): Store at room temperature below 86 degrees F for up to 56 days. Do not refrigerate after first use.

Note: Toujeo has a significantly longer in-use period (56 days) compared to insulin glargine 100 units/mL products (28 days). Patients switching between products must be counseled on this difference.

Do not transfer Toujeo from the pen cartridge into a syringe. Toujeo is 3 times more concentrated than U-100 insulins; use of a U-100 syringe would result in a severe overdose.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from Lantus (insulin glargine 100 units/mL) to Toujeo, a higher daily dose of Toujeo will typically be needed to maintain the same level of glycemic control. Titrate based on blood glucose response.

When switching from once-daily long- or intermediate-acting insulin to Toujeo, start at the same unit dose.

When switching from twice-daily long- or intermediate-acting insulin (NPH) to Toujeo, start at 80 percent of the total daily dose.

Monitor blood glucose frequently during the first weeks of therapy.

Do not dilute or mix Toujeo with any other insulin or solution.

3. Insulin Pump Use Instructions:

Not approved for pump use. Toujeo must not be administered intravenously or used in an insulin infusion pump.

Tresiba (insulin degludec)

Application: BLA203314 | **Manufacturer:** Novo Nordisk | **Customer Service:** 1-800-727-6500 |

Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials and FlexTouch pens (U-100 and U-200): Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 56 days.

In-use FlexTouch pens (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 56 days.

Note: The 56-day in-use limit applies regardless of whether the product is stored refrigerated or at room temperature.

Do not transfer Tresiba U-200 from the pen into a syringe. Syringe scales are calibrated for U-100 only; use of a U-100 syringe with U-200 insulin would result in a severe overdose.

For pediatric patients requiring less than 5 units per day, use the U-100 vial only.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from any long- or intermediate-acting insulin to Tresiba in adults (type 1 or type 2 diabetes), start at the same unit dose as the total daily long- or intermediate-acting insulin dose.

When switching from any long- or intermediate-acting insulin to Tresiba in pediatric patients (age 1 year and older), start at 80 percent of the total daily long- or intermediate-acting insulin dose to minimize the risk of hypoglycemia.

For insulin-naïve adults with type 2 diabetes, the starting dose is 10 units once daily.

Recommended interval between dose adjustments is 3 to 4 days.

In patients with type 1 diabetes, Tresiba must be used concomitantly with short-acting insulin.

Monitor blood glucose frequently during any regimen change.

Do not dilute or mix Tresiba with any other insulin or solution.

3. Insulin Pump Use Instructions:

Not approved for pump use. Tresiba must not be administered intravenously or used in an insulin infusion pump.

ONCE-WEEKLY LONG-ACTING INSULINS

Ultra long-acting insulins provide extended basal insulin coverage for one week. Awiqli (insulin icodec) is a once-weekly basal insulin.

Awiqli (insulin icodec-abae)

1. Storage Instructions:

Unopened FlexTouch pens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

In-use pens (opened): May be stored at room temperature below 86 degrees F or refrigerated at 36 degrees F to 46 degrees F for up to 12 weeks. The 12-week limit applies regardless of storage location.

Do not freeze. Avoid direct sunlight, heat, and microwaves. Keep the pen cap on when not in use.

Do not use a syringe to withdraw Awiqli from the pen. Awiqli is a U-700 concentration; use of a U-100 syringe could result in a severe overdose.

Doses are dialed in 10-unit increments only (minimum 10 units, maximum 700 units per injection). If a dose greater than 700 units is required, split into two injections.

2. Switching Instructions:

Awiqli requires a structured two-week transition protocol when switching from a daily basal insulin.

Week 1 (one-time loading dose): Administer the first Awiqli dose on the day after the last dose of daily basal insulin. The Week 1 dose equals the previous total daily basal dose multiplied by 7, then multiplied by 1.5, rounded to the nearest 10 units.

Week 2: Administer a dose equal to the previous total daily basal dose multiplied by 7, rounded to the nearest 10 units.

Week 3 onward: Titrate based on metabolic needs, blood glucose monitoring, and glycemic control goals.

When switching from Awiqli to a daily basal insulin: Because insulin icodec has a half-life of approximately one week, its glucose-lowering effect persists for several days after the last dose. Switching to the new daily basal insulin should be done under close medical supervision with increased blood glucose monitoring. Monitor blood glucose closely to avoid hypoglycemia.

For insulin-naïve patients: Starting dose is 70 units subcutaneously once weekly.

Monitor blood glucose closely during any transition. Doses and timing of concurrent rapid-acting or short-acting insulin may need adjustment.

Do not mix Awiqli with any other insulin or solution.

3. Insulin Pump Use Instructions:

Not approved for pump use. Awiqli must not be administered intramuscularly, intravenously, or in an insulin infusion pump. Do not draw Awiqli from the pen into a syringe.

COMBINATION/PREMIKED INSULINS

Premixed insulin products contain a fixed ratio of intermediate-acting and short- or rapid-acting insulin. They are not suitable for flexible mealtime dosing regimens and must not be used in insulin infusion pumps.

Humulin 70/30 (70% insulin isophane human / 30% insulin human)

Application: BLA019717 | Manufacturer: Lilly | Customer Service: 1-800-545-5979 | Label:

[DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened 10 mL and 3 mL vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. At room temperature below 86 degrees F, use within 31 days total (combined unopened and in-use time).

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 31 days.

Unopened 3 mL KwikPen: Store in a refrigerator until the expiration date. At room temperature below 86 degrees F, use within 10 days total.

In-use 3 mL KwikPen (opened): Store at room temperature below 86 degrees F for up to 10 days. Do not refrigerate after first use.

Do not freeze. Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to Humulin 70/30, dosage adjustment may be needed.

The proportion of intermediate- and short-acting insulin is fixed; independent adjustment of basal or prandial dose is not possible.

Do not mix Humulin 70/30 with any other insulins or diluents.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

3. Insulin Pump Use Instructions:

Not approved for pump use. Humulin 70/30 must not be used in an insulin infusion pump.

Humalog Mix 50/50 (50% insulin lispro protamine / 50% insulin lispro)

Application: BLA021018 | Manufacturer: Lilly | Customer Service: 1-800-545-5979 | Label:

[DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened 10 mL vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. At room temperature below 86 degrees F, use within 28 days total.

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 28 days.

Unopened 3 mL KwikPen: Store in a refrigerator until the expiration date. At room temperature below 86 degrees F, use within 10 days total.

In-use 3 mL KwikPen (opened): Store at room temperature below 86 degrees F for up to 10 days. Do not refrigerate after first use.

Do not freeze. Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to Humalog Mix 50/50, dosage adjustment may be needed.

Do not mix Humalog Mix 50/50 with any other insulins or diluents.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

3. Insulin Pump Use Instructions:

Not approved for pump use. Humalog Mix 50/50 must not be used in an insulin infusion pump.

Humalog Mix 75/25 (75% insulin lispro protamine / 25% insulin lispro)

Application: BLA021017 | **Manufacturer:** Lilly | **Customer Service:** 1-800-545-5979 | **Label:** [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened 10 mL vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. At room temperature below 86 degrees F, use within 28 days total.

In-use vials (opened): May be stored refrigerated or at room temperature below 86 degrees F for up to 28 days.

Unopened 3 mL KwikPen: Store in a refrigerator until the expiration date. At room temperature below 86 degrees F, use within 10 days total.

In-use 3 mL KwikPen (opened): Store at room temperature below 86 degrees F for up to 10 days. Do not refrigerate after first use.

Note: The KwikPen has a significantly shorter room-temperature window (10 days) than the vial (28 days). Patients must be counseled on this difference.

Do not freeze. Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to Humalog Mix 75/25, dosage adjustment may be needed.

Humalog Mix 75/25 contains a rapid-acting insulin analog and should be injected within 15 minutes before or after the start of a meal.

Do not mix Humalog Mix 75/25 with any other insulins or diluents.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

3. Insulin Pump Use Instructions:

Not approved for pump use. Humalog Mix 75/25 must not be used in an insulin infusion pump.

Novolin 70/30 (70% human insulin isophane / 30% human insulin)

Application: BLA019991 | Manufacturer: Novo Nordisk | Customer Service: 1-800-727-6500 |
Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze. At room temperature below 77 degrees F, use within 42 days total.

In-use vials (opened): May be stored at room temperature below 77 degrees F for up to 42 days.

Unopened 3 mL FlexPen: Store in a refrigerator until the expiration date. At room temperature below 86 degrees F, use within 28 days.

In-use 3 mL FlexPen (opened): Store at room temperature below 86 degrees F for up to 28 days. Do not refrigerate after first use.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to Novolin 70/30, dosage adjustment may be needed.

Do not mix Novolin 70/30 with any other insulins or diluents.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

3. Insulin Pump Use Instructions:

Not approved for pump use. Novolin 70/30 must not be used in an insulin infusion pump.

NovoLog Mix 70/30 (70% insulin aspart protamine / 30% insulin aspart)

Application: BLA021172 | Manufacturer: Novo Nordisk | Customer Service: 1-800-727-6500 |
Label: [DailyMed Prescribing Information](#)

1. Storage Instructions:

Unopened 10 mL vials and FlexPens: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze.

Unopened 10 mL vials: Store in a refrigerator at 36 degrees F to 46 degrees F until the expiration date. Do not freeze. At room temperature below 86 degrees F, use within 28 days.

In-use vials (opened): May be stored in a refrigerator or at room temperature below 86 degrees F for up to 28 days.

Unopened 3 mL FlexPen: Store in a refrigerator until the expiration date. At room temperature below 86 degrees F, use within 14 days.

In-use 3 mL FlexPen (opened): Store at room temperature below 86 degrees F for up to 14 days.

Resuspend immediately before use by rolling the vial 10 times or rolling and inverting the FlexPen 10 times each.

Protect from direct heat and light. Discard if frozen.

2. Switching Instructions:

When switching from another insulin to NovoLog Mix 70/30, dosage adjustment may be needed.

NovoLog Mix 70/30 contains a rapid-acting insulin analog and should be injected within 15 minutes before the start of a meal (or after meal initiation in type 2 diabetes).

Do not mix NovoLog Mix 70/30 with any other insulins or diluents.

Make all regimen changes under close medical supervision with increased blood glucose monitoring.

3. Insulin Pump Use Instructions:

Not approved for pump use. NovoLog Mix 70/30 must not be administered intravenously or used in an insulin infusion pump.