

company announcement

Awikli® approved in the US, the first and only once-weekly basal insulin treatment for adults with type 2 diabetes

- Awikli® (insulin icodec-abae) injection is the first-ever once-weekly basal insulin approved by the FDA
- Awikli® offers adults with type 2 diabetes an alternative to daily basal insulin injections, reducing these injections from seven to one per week
- Novo Nordisk expects to launch Awikli® nationwide in the US in the second half of 2026.

Bagsværd, Denmark, 27 March 2026 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved Awikli® (insulin icodec-abae) injection 700 units/mL, the first and only once-weekly, long-acting basal insulin, indicated as an adjunct to diet and exercise to improve glycaemic control (blood sugar) in adults living with type 2 diabetes. The approval offers the only once-weekly basal insulin option, providing a new treatment solution that fits different patient routines and preferences for adults living with type 2 diabetes.

The approval is based on results from the ONWARDS phase 3a programme in type-2-diabetes for once-weekly Awikli® injection, which comprises four randomised, active-controlled, treat-to-target trials in approximately 2,680 adults with uncontrolled type 2 diabetes, used in combination with a mealtime insulin or in combination with common oral anti-diabetic agents and/or GLP-1 receptor agonists. The clinical programme evaluated once-weekly Awikli® vs daily basal insulin and demonstrated efficacy in the primary endpoint of HbA_{1c} reduction across the ONWARDS pivotal clinical trial programme in adults with type 2 diabetes. Across ONWARDS trials, the safety profile of Awikli® was overall consistent with the daily basal insulin class.

“The Awikli® approval reflects Novo Nordisk’s ongoing efforts to advance healthcare innovation and strengthen support for people living with diabetes. As the first FDA-approved, once-weekly basal insulin for adults with type 2 diabetes, it offers an important new treatment option. At a time when parts of the industry are stepping back from insulin, we are reaffirming our commitment - continuing to invest in innovation, access, and supply for the millions of patients who rely on insulin every day,” said Mike Doustdar, president and CEO of Novo Nordisk.

Novo Nordisk expects to launch Awikli® in the FlexTouch® device in the US in the second half of 2026. Awikli® is now approved in the US, EU, and 13 additional countries, with market-specific indications for diabetes.

About Awikli®

Awikli® (insulin icodec-abae) injection 700 units/mL is a prescription medicine and is the first and only FDA-approved once-weekly basal insulin indicated as an adjunct to diet and exercise for adults with type 2 diabetes. Awikli® is designed as an alternative to daily basal insulin, and its approval is supported by the ONWARDS clinical programme, which evaluated its efficacy and safety across diverse adult populations living with type 2 diabetes. Awikli® is administered once weekly on the same day each week using the Awikli® FlexTouch® device.

About Novo Nordisk

Novo Nordisk is a leading global healthcare company founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 68,800 people in 80 countries and markets its products in around 170 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit [novonordisk.com](https://www.novonordisk.com), [Facebook](#), [Instagram](#), [X](#), [LinkedIn](#) and [YouTube](#).

Publication of inside information pursuant to Market Abuse Regulation, Article 17.

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