

# backgrounder

## Tresiba® (insulin degludec injection 200 Units/mL)

### Product Description

- Tresiba® is a once-daily, long-acting basal insulin that is approved for blood sugar control in adults with diabetes<sup>1</sup>
  - Basal insulin, such as Tresiba®, gives the body insulin throughout the day and night. It helps control blood sugar between meals and during sleep
  - Tresiba® is a long-acting insulin that lasts at least 42 hours after the last of 8 once-daily injections (0.4 U/kg), and has a consistently flat and stable profile at steady state<sup>1-3</sup>
  - Patients who miss a dose of Tresiba® should inject their daily dose during waking hours upon discovering the missed dose and then continue with their regular dosing schedule, making sure there are at least 8 hours between Tresiba® injections<sup>1</sup>
- On September 25, 2015, Tresiba® was approved by the US Food and Drug Administration (FDA)

### Clinical Data

- Tresiba® was studied in the BEGIN® clinical trial program, which includes 9 randomized, controlled, treat-to-target, open-label trials in adult patients with type 1 and type 2 diabetes from over 40 countries<sup>4</sup>
- The FDA approved Tresiba® based on data showing that Tresiba® improves blood sugar control, achieving comparable A1C reductions to FDA-approved insulin comparators. Tresiba® met the prespecified noninferiority margin (0.4%)<sup>4</sup>

### Dosage and Delivery

- Tresiba® is available in 100 units/mL or 200 units/mL FlexTouch® pens
- Tresiba® FlexTouch® 200 units/mL (U-200) can deliver up to 160 units of insulin in a single injection<sup>1</sup>
  - Tresiba® U-200 FlexTouch® contains a total of 600 units of insulin per pen, dosed in 2-unit increments<sup>1</sup>
- Tresiba® FlexTouch® 100 units/mL (U-100) can deliver up to 80 units of insulin in a single injection<sup>1</sup>
  - Tresiba® U-100 FlexTouch® contains a total of 300 units of insulin per pen, dosed in 1-unit increments<sup>1</sup>

**Please see next page for Important Safety Information.**

- Tresiba® FlexTouch® is a prefilled insulin pen that offers several key features, including:
  - A dosing mechanism that ensures the push button does not extend at any dose<sup>5-7</sup>
  - Compatibility with NovoFine®, NovoFine® Plus, and NovoTwist® needles and all universal fit needles<sup>a</sup>
- Tresiba® lasts 8 weeks without refrigeration once in use, if kept at room temperature below 86°F<sup>1</sup>

<sup>a</sup>Needles are sold separately and may require a prescription in some states.

## What is Tresiba®?

- Prescription Tresiba® is a long-acting insulin used to control high blood sugar in adults with diabetes
- Tresiba® is not for people with diabetic ketoacidosis
- Tresiba® is available in 2 concentrations: 200 units/mL and 100 units/mL
- It is not known if Tresiba® is safe and effective in children under 18 years of age

## Important Safety Information

**Do not share your Tresiba® FlexTouch® 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.**

### Who should not take Tresiba®?

**Do not take Tresiba® if you:**

- are having an episode of low blood sugar
- are allergic to Tresiba® or any of the ingredients in Tresiba®

**Before taking Tresiba®, tell your health care provider about all your medical conditions, including if you are:**

- pregnant, planning to become pregnant, or are breastfeeding
- taking new prescription or over-the-counter medicines, vitamins, or herbal supplements

**Talk to your health care provider about low blood sugar and how to manage it.**

### How should I take Tresiba®?

- **Read the Instructions for Use** and take Tresiba® exactly as your health care provider tells you to
- **Do not do any conversion of your dose. The dose counter always shows the selected dose in units**

**Please see additional Important Safety Information on the next page.**

## Important Safety Information (cont'd)

### How should I take Tresiba®? (cont'd)

- Know the type and strength of insulin you take. **Do not** change the type of insulin you take unless your health care provider tells you to
- If you miss or are delayed in taking your dose of Tresiba®:
  - Take your dose as soon as you remember, then continue with your regular dosing schedule
  - Make sure there are at least 8 hours between doses
- **Check your blood sugar levels.** Ask your health care provider what your blood sugar levels should be and when you should check them
- **Do not reuse or share your needles with other people.** You may give them a serious infection, or get a serious infection from them
- **Never** inject Tresiba® into a vein or muscle
- **Never** use a syringe to remove Tresiba® from the FlexTouch® pen

### What should I avoid while taking Tresiba®?

- **Do not** drive or operate heavy machinery, until you know how Tresiba® affects you
- **Do not** drink alcohol or use prescription or over-the-counter medicines that contain alcohol

### What are the possible side effects of Tresiba®?

#### Tresiba® may cause serious side effects that can be life-threatening, including:

- **Low blood sugar (hypoglycemia).** Signs and symptoms that may indicate low blood sugar include anxiety, irritability, mood changes, dizziness, sweating, confusion, and headache
- **Low potassium in your blood (hypokalemia)**
- **Heart failure** in some people if taken with thiazolidinediones (TZDs). This can happen even if you have never had heart failure or heart problems. If you already have heart failure, it may get worse while you take TZDs with Tresiba®. Tell your health care provider if you have any new or worse symptoms of heart failure including shortness of breath, tiredness, swelling of your ankles or feet, and sudden weight gain

**Your insulin dose may need to change because of** change in level of physical activity or exercise, increased stress, change in diet, weight gain or loss, or illness.

**Common side effects may include** reactions at the injection site, itching, rash, serious allergic reactions (whole body reactions), skin thickening or pits at the injection site (lipodystrophy), weight gain, and swelling of your hands and feet.

**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, or confusion.

Please [click here](#) for Prescribing Information.

For more information about Tresiba®, please visit [Media.Tresiba.com](http://Media.Tresiba.com).

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## References

1. Tresiba [package insert]. Plainsboro, NJ: Novo Nordisk Inc; September 2015.
2. Heise T, Hermanski L, Nosek L, Feldman A, Rasmussen S, Haahr H. *Diabetes Obes Metab.* 2012;14(9):859-864.
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6. Oyer D, Narendran P, Qvist M, Niemeyer M, Nadeau DA. *Expert Opin Drug Deliv.* 2011;8(10):1259-1269.
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