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Insulin degludec

# Insulin degludec

Generic name: insulin degludec

Brand name: Tresiba

Dosage form: pen and vial for subcutaneous injection

Drug class: Insulin

Medically reviewed by Philip Thornton, DipPharm. Last updated on Aug 23, 2023.

Uses Warnings Before taking Dosage Side effects Interactions FAQ

## What is insulin degludec?

Insulin degludec is a long-acting basal human insulin analog that is used to improve glycemic control in people with diabetes.

Insulin is a hormone produced by your body that helps you to lower your blood glucose (blood sugar) levels.

People with type 1 diabetes and some people with type 2 diabetes need to administer man-made forms of insulin. This is because they don't produce enough insulin themselves or their body doesn't respond well enough to the insulin they produce.

Basal insulin analogs like insulin degludec, work to keep your blood glucose levels stable during times when you're fasting, such as at night when you're asleep. Insulin degludec provides a 'background', slow-acting supply of insulin.

Insulin degludec was approved by the US Food and Drug Administration (FDA) in 2015. The Tresiba brand of insulin degludec is the only version of this medication currently available.

## What is insulin degludec used for?

- Insulin degludec is used to control high blood sugar in adults and children who are 1 year of age and older with diabetes mellitus.
- Insulin degludec is not for people with diabetic ketoacidosis (increased ketones in the blood or urine).
- It is not known if insulin degludec is safe and effective in children under 1 year of age.
- Insulin degludec is available in 2 concentrations (U-100 and U-200):
  - U-100 concentration is available in pen and vial
    - The 100 units/mL pen can be injected from 1 to 80 units in a single injection, in increments of 1 unit.
    - The 100 units/mL vial should be used with a U-100 insulin syringe only.

- U-200 concentration is only available in pen
  - The 200 units/mL pen can be injected from 2 to 160 units in a single injection, in increments of 2 units.

## Important information

Do not share your insulin degludec FlexTouch insulin delivery device (pen) with other people, even if the needle has changed. Do not share needles or syringes with another person. You may give other people a serious infection, or get a serious infection from them.

## Who should not take insulin degludec?

Do not take insulin degludec if you:

- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to insulin degludec or any of the ingredients in insulin degludec. See below for a complete list of ingredients.
- 1 Insulin degludec pregnancy and breastfeeding warnings (more detail)

## What should I tell my doctor before taking insulin degludec?

Before taking insulin degludec, tell your healthcare 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.

Before you start taking insulin degludec, talk to your healthcare provider about low blood sugar and how to manage it.

## How should I take insulin degludec?

- Read the Instructions for Use that come with your insulin degludec.
- Take insulin degludec exactly as your healthcare provider tells you to.
- Do not do any conversion of your dose. The dose counter always shows the selected dose in units. Both the 100 units/mL and 200 units/mL insulin degludec FlexTouch pens are made to deliver your insulin dose in units.
- Know the type and strength of insulin you take. Do not change the type of insulin you take 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.
- For children who need less than 5 units of insulin degludec each day, use a insulin degludec U-100 vial.
- Check your blood sugar levels. Ask your healthcare provider what your blood sugars should be and when you should check your blood sugar levels.
- 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.
- Never inject insulin degludec into a vein or muscle.

- Never use a syringe to remove insulin degludec from the FlexTouch pen.
- Insulin degludec can be injected under the skin (subcutaneously) of your upper legs (thighs), upper arms, or stomach area (abdomen).
- 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.
  - o Do not use the exact same spot for each injection.
  - o Do not inject where the skin has pits, is thickened, or has lumps.
  - o Do not inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.

### What happens if I miss a dose?

- Adults: If you miss or are delayed in taking your dose of insulin degludec:
  - Take your dose as soon as you remember then continue with your regular dosing schedule.
  - Make sure there are at least 8 hours between your doses.
- If children miss a dose of insulin degludec:
  - Call the healthcare provider for information and instructions about checking blood sugar levels more often until
    the next scheduled dose of insulin degludec.

## What should I avoid while taking insulin degludec?

While taking insulin degludec do not:

- Drive or operate heavy machinery, until you know how insulin degludec affects you.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

## **Dosing information**

- Inject insulin degludec subcutaneously into the thigh, upper arm, or abdomen.
- Rotate injection sites to reduce risk of lipodystrophy and localized cutaneous amyloidosis.
- For pediatric patients requiring less than 5 units of insulin degludec each day, use a U-100 vial.
- In adults, inject subcutaneously once daily at any time of day.
- In pediatric patients inject subcutaneously once daily at the same time every day.
- Individualize dose based on type of diabetes, metabolic needs, blood glucose monitoring results and glycemic control
  goal.
- The recommended days between dose increases are 3 to 4 days.

### Starting dose in patients who are not taking insulin:

Type 1 diabetes

The recommended starting dose of insulin degludec in insulin naive patients with type 1 diabetes is approximately one-third to one-half of the total daily insulin dose. The remainder of the total daily insulin dose should be administered as a short-acting insulin and divided between each daily meal. As a general rule, 0.2 to 0.4 units of insulin per kilogram of body weight can be used to calculate the initial total daily insulin dose in insulin naive patients with type 1 diabetes.

Type 2 diabetes

The recommended starting dose of insulin degludec in insulin naïve patients with type 2 diabetes mellitus is 10 units once daily.

### Starting dose in patients already taking insulin:

- Adults with type 1 or type 2 diabetes
   Start insulin degludec at the same unit dose as the total daily long or intermediate-acting insulin unit dose.
- Pediatric patients (≥ 1 year of age) with type 1 or type 2 diabetes
   Start insulin degludec at 80 percent of the total daily long or intermediate-acting insulin unit dose to minimize the risk of hypoglycemia

See full prescribing information for additional important information about insulin degludec dosing.

1 Detailed Insulin degludec dosage information

### What are the side effects of insulin degludec?

Insulin degludec 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
  - o blurred vision
  - o anxiety, irritability, or mood changes
  - sweating
  - slurred speech
  - hunger
  - confusion
  - shakiness
  - headache
  - fast heartbeat
- Low potassium in your blood (hypokalemia).
- Heart failure. Taking certain diabetes pills called thiazolidinediones or "TZDs" with insulin degludec 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 insulin degludec. Your healthcare provider should monitor you closely while you are taking TZDs with insulin degludec. Tell your healthcare 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. Treatment with TZDs and insulin degludec may need to be adjusted 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
- · weight gain or loss
- increased stress
- illness
- · change in diet

Common side effects of insulin degludec may include:

- serious allergic reactions (whole body reactions)
- · reactions at the injection site
- skin thickening or pits at the injection site (lipodystrophy)
- itching
- rash
- swelling of your hands and feet
- · 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 insulin degludec. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Insulin degludec side effects (more detail)

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### Interactions

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

Especially tell your doctor if you take medications that may:

- increase your risk of hypoglycemia (low blood sugar)
- increase or decrease how well insulin degludec works
- · make it hard to tell if your blood sugar is getting too low

Ask your healthcare provider or pharmacist if you are not sure if you take one of these medications.

Insulin degludec drug interactions (more detail)

## Does insulin degludec interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

insulin degludec
+
Enter a drug name
Add

## Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant. There is a risk to mother and fetus associated with poorly controlled diabetes in pregnancy. However, there is a lack of data available to determine whether insulin degludec is safe in pregnancy.

Tell your doctor if you are breastfeeding or plan to breastfeed. There is a lack of data available to determine whether insulin degludec is safe to use while breastfeeding. Talk to your doctor about whether the benefits of taking insulin degludec while breastfeeding outweigh any possible risks. Talk to your doctor about the best way to feed your baby while

taking insulin degludec.

## **Storage**

Vials before use:

- Store unopened insulin degludec vials in the refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light.
- Do not freeze insulin degludec. Do not use insulin degludec if it has been frozen.
- Unused insulin degludec vials may be used until the expiration date printed on the label, if they are kept in the refrigerator.
- After 56 days, throw away insulin degluded vials that have been kept at room temperature (below 86°F (30°C)).

#### Vials in use:

- Store the insulin degludec vial you are currently using in the refrigerator between 36°F to 46°F (2°C to 8°C) or keep at room temperature below 86°F (30°C) in the original carton to protect from light.
- Keep insulin degludec away from direct heat or light.
- The insulin degludec vial you are using should be thrown away after 56 days, even if it still has insulin left in it and the expiration date has not passed.

#### Pen before use:

- Store unused insulin degludec FlexTouch Pens in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Do not freeze insulin degludec. Do not use insulin degludec if it has been frozen.
- Unused Pens may be used until the expiration date printed on the label, if kept in the refrigerator.

#### Pen in use:

- Store the Pen you are currently using in the refrigerator between 36°F to 46°F (2°C to 8°C) or keep at room temperature below 86°F (30°C).
- · Keep insulin degludec away from heat or light.
- The insulin degludec FlexTouch Pen you are using should be thrown away after 56 days if it is refrigerated or kept at room temperature, even if it still has insulin left in it and the expiration date has not passed.

## What are the ingredients in insulin degludec?

Active Ingredient: insulin degludec

Inactive Ingredients: glycerol, metacresol, phenol, water for injection, and zinc. Hydrochloric acid or sodium hydroxide may be added.

Insulin degludec is manufactured under the brand name Tresiba by Novo Nordisk A/S, DK-2880 Bagsværd, Denmark.

## Insulin degludec Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

### Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for insulin degludec.

#### Tresiba (insulin degludec) - Novo Nordisk Inc.

Formulation type	Strength
Autoinjector	300 units/3 mL (100 units/mL)
Autoinjector	600 units/3 mL (200 units/mL)
Multi-Dose Vial	1,000 units/10 mL (100 units/mL)

View Tresiba information in detail.

### **Popular FAQ**

How and where should I inject insulin?

What is the difference between Soliqua and Xultophy?

### More FAQ

- Toujeo vs Tresiba What's the difference between them?
- Is Tresiba the same as Lantus?
- Does Tresiba cause weight gain?
- How long does Tresiba last?
- How do I use the Tresiba FlexTouch pen?
- What are the ingredient drugs in Ryzodeg 70/30?

View more FAQ...

#### References

- 1. National Library of Medicine Tresiba Product Label
- 2. Vora J, Cariou B, Evans M, et al. Clinical use of insulin degludec. Diabetes Res Clin Pract. 2015;109(1):19-31. doi:10.1016/j.diabres.2015.04.002

## More about insulin degludec

· Check interactions

- Compare alternatives
- Pricing & coupons
- Reviews (154)
- Side effects
- Dosage information
- During pregnancy
- Support group
- Drug class: insulin
- En español

### **Patient resources**

- Insulin Degludec (U-100) Prefilled Pens patient information
- Insulin Degludec (U-100) Vials
- Insulin Degludec (U-200) Prefilled Pens

#### Other brands

Tresiba

### **Professional resources**

- Insulin Degludec monograph
- Insulin Degludec (FDA)

#### Other brands

Tresiba

### Related treatment guides

- Type 2 Diabetes
- Diabetes, Type 1
- Diabetes Mellitus

### **Further information**

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

**Medical Disclaimer** 

#### **Availability**

Rx Prescription only

### **Pregnancy & Lactation**

ം Risk data available

**CSA Schedule\*** 

N/A Not a controlled drug

#### **Approval History**

□ Drug history at FDA

#### **User Reviews & Ratings**

4.3 / 10

154 Reviews

#### **Images**

Tresiba (insulin degludec) 100 units/mL (U-100) single-patient-use FlexTouch Pen





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