



Your Tresiba® guide

Information for you who use Tresiba® basal insulin



TRESIBA®
insulin degludec [rDNA origin] injection

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Dear Tresiba® insulin user

Your doctor has prescribed you Tresiba® insulin (insulin degludec) for the treatment of you diabetes. Before starting the treatment, please read the patient leaflet carefully.

These instructions contain information on Tresiba® insulin and how to use it. Tresiba® is a long-acting basal insulin called insulin degludec. It is used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above. It is used for once-daily dosing. In type 1 diabetes mellitus, Tresiba® must always be used in combination with meal-related rapid-acting insulins.

This leaflet contains information on how the insulin works, how to inject the insulin and what you should be aware of when taking insulin.

The content of this leaflet does not replace the instructions you have received from your doctor or nurse.

Novo Nordisk wants to support you with the daily management of your diabetes.

We offer the following services:

novoInfo
novoinfo@novonordisk.fi

A guide to carbohydrates for your mobile phone

A digital, free of charge carbohydrate guide supports your diet when you have insulin treated diabetes.

The app is available in Finnish and Swedish for Android and iOS mobile phones. It can be found on App Store and Google Play with the keywords "Novo Nordisk" and "mobiilihiilihydraattikäsikirja".

Best regards,
Novo Nordisk Farma Oy

Treatment with Tresiba®

What Tresiba® is and what it is used for

- Tresiba® is a long-acting basal insulin used to control high blood sugar in adults and children as young as 1 year old with diabetes.
- Tresiba® releases slow and steady, to closely mimic the body's long-acting (basal) rate of insulin release.

How to use Tresiba®

- Use Tresiba® once each day, preferably at the same time every day. Always follow your doctor's or nurse's recommendation for dose.
- On occasions when it is not possible to take Tresiba® at the same time of the day, it can be taken at a different time of day. **Make sure to have a minimum of 8 hours and maximum of 40 hours between the doses.**
- If you forget a dose, inject the missed dose when discovering the mistake, ensuring a minimum of 8 hours between doses. If you discover that you missed your previous dose when it is time to take your next regular scheduled dose, **do not inject a double dose**, but resume your once-daily dosing schedule.

Tresiba® is injected under the skin

- Similarly to other insulins, Tresiba® is given as an injection under the skin (subcutaneously). The best places to inject are the front of your thighs, upper parts of the buttocks or your abdomen.
- Change the place within the area where you inject each day to reduce the risk of developing lumps and skin pitting, known as lipodystrophy.
- The fatty tissue under the skin may get thicker if you keep injecting insulin in the same place. Changing where you inject each time may help prevent the development of these skin changes. If you keep injecting in the same place, these reactions can become more severe and affect the amount of medicine your body gets from the pen. The risk of lipodystrophy concerns all insulin treatments.

What to consider when transferring to Tresiba®

- The full effect of Tresiba® can be determined approximately one week after the first dose.
- Potential increases in blood sugar levels are corrected with extra bolus insulin if necessary.

It's recommended to adjust the dose no more often than once a week. Changes in the units of the dose is done based on individual needs. Your doctor or nurse gives you more detailed information on dose adjustment.

Injecting with Tresiba® FlexTouch®



Tresiba® FlexTouch® 100 units/ml has a light green packaging and label and contains 300 units. The pen can provide a dose of 1–80 units in one injection in steps of 1 unit.

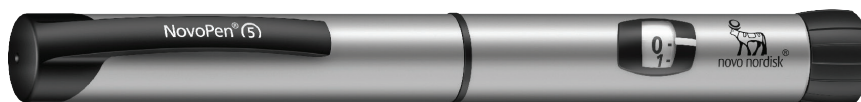


Tresiba® FlexTouch® 200 units/ml has a dark green packaging and label and contains 600 units. The pen can provide a dose of 2–160 units in one injection in steps of 2 units.

The Tresiba® FlexTouch® pen is designed to be used with NovoFine® single-use disposable needles. Remember to use a new needle for each injection. Store your pen without the needle attached.

Injecting with NovoPen®

Tresiba® 100 units/ml is also available in a Novo Nordisk Penfill® 3 ml cartridge compatible with NovoPen® insulin pens. Due to safety reasons Tresiba® 200 units/ml is not available in a 3 ml Penfill® cartridge.



NovoPen® 5 insulin pen is a durable pen with a built-in memory function. You can select up to 60 units per dose in steps of 1 unit. NovoPen® is compatible with 100 units/ml Penfill® 3 ml cartridges and NovoFine® needles.



NovoPen Echo® insulin pen is a durable pen with a built-in memory function. You can select up to 30 units per dose in steps of 0,5 units. NovoPen® is compatible with 100 units/ml Penfill® 3 ml cartridges and NovoFine® needles.

Please read the instructions for the insulin pen carefully before the first injection.

Using Tresiba® in special situations

Changes in injection routines

It is possible to take once-daily Tresiba® at any time of the day, if needed, but it is recommended to take the Tresiba® dose at the same time every day. Sometimes it might not be possible to take Tresiba® at the same time of the day, e.g. when traveling or if you have forgotten to take your basal insulin. However, always make sure to have a minimum of 8 hours between the doses.

Sickness

You should not discontinue the insulin treatment when you are sick. Your insulin requirement might increase if you have fever or have had surgery. On the other hand, if you suffer from vomiting your insulin requirement might decrease. Your healthcare provider will instruct you on your insulin dosage during illness.

Other medicines and Tresiba®

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. Some medicines affect your blood sugar level, this may mean your insulin dose has to be changed.

Alcohol

If you drink alcohol, your need for insulin may change. Your blood sugar level may either rise or fall. It can also be more difficult to identify hypoglycaemia if a person is intoxicated. You should therefore monitor your blood sugar level more often than usual.

How to store Tresiba®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pen label and carton, after 'EXP'. The expiry date refers to the last day of that month.

Before first use

Store unopened pens in a refrigerator (+2°C to +8°C). Do not freeze. Keep away from the freezing element.

After first opening or if carried as a spare

You can carry your Tresiba® pre-filled pen (FlexTouch®) with you and keep it at room temperature (not above +30°C) or in a refrigerator (+2°C to +8°C) for up to 8 weeks. Always keep the cap on the pen when you are not using it in order to protect it from light. Store the pen without the needle attached.

When traveling

Ask your nurse for a Medical Certificate in good time before your flight to make sure that you can pack your insulin pens and needles in your carry-on luggage.

Qualities of the FlexTouch® insulin pen

Tresiba® in a pre-filled pen is available in two strengths. “Tresiba® 100 units/ml” or “Tresiba® 200 units/ml” is clearly marked on the pen label and packaging. In addition, Tresiba® 100 units/ml packaging and label are light green, and Tresiba® 200 units/ml packaging and label are dark green with striping with a red box highlighting the formulation strength.

Ensuring you use the right type of insulin – always check the insulin label before each injection to avoid accidental mix-ups between different strengths of Tresiba® as well as other insulin products.

Tresiba® 100 units/ml

light green



3 ml contains 300 units of insulin
max dose 80 units

Tresiba® 200 units/ml

dark green



3 ml contains 600 units of insulin
max dose 160 units

Your doctor will decide which strength is the best for you. Turn the dose selector to select the dose you need, as directed by your doctor or nurse. Always read the instructions carefully before using your FlexTouch® pre-filled pen.

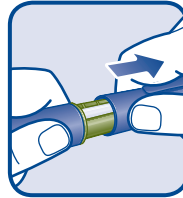
The pens are equipped with a dose counter that shows the units selected. **Only the dose counter and dose pointer will show how many units you select per dose.** Do not change the dose if you switch between the two strengths.

Do not use a syringe to remove the solution from the pen to avoid dosing errors and potential overdose.

Injecting with FlexTouch[®]

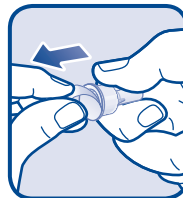
twist, inject, ready

Twist

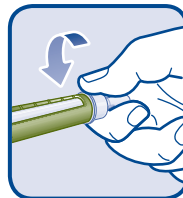


Check the name and strength on the label.

Remove the cap.

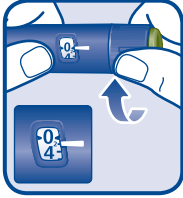


Take a new needle and tear off the paper tab.



Push the needle straight onto the pen. Turn until it is on tight. Pull off the outer needle cap and keep it for later. Pull off the inner needle cap and throw it away. If you try to put it back on, you may accidentally stick yourself with the needle.

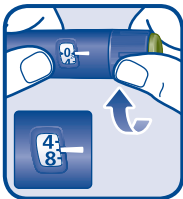
Inject



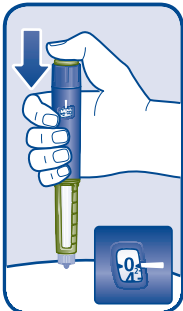
Check the insulin flow by turning the dose selector to select 2 units. Hold the pen with the needle pointing up. Tap the top of the pen gently a few times.



Press and hold in the dose button until the dose counter returns to 0. A drop of insulin should appear at the needle tip.

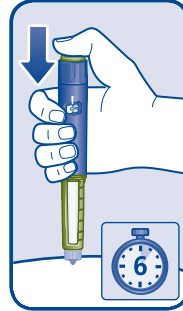


Turn the dose selector to select the dose you need, as directed by your doctor or nurse. The dose counter and dose pointer show how many units you have selected. In the image 6 units are selected as an example.



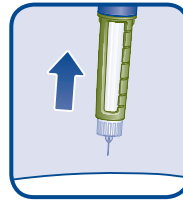
Insert the needle into your skin and make sure you can see the dose counter. Press and hold down the dose button until the dose counter returns to 0.

Ready

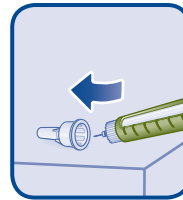


You may hear or feel a click when the dose pointer lines up with 0.

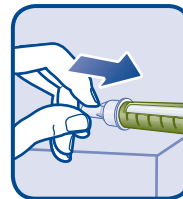
Leave the needle under the skin for at least 6 seconds to make sure you get your full dose.



Pull the needle and pen straight up from your skin. Keep holding the dose button down.



Lead the needle tip into the outer needle cap on a flat surface without touching the needle or the outer needle cap. Carefully push the outer needle cap completely on.



Unscrew the needle and dispose of it carefully. Put the pen cap back on your pen.

If you have any additional questions about using Tresiba® FlexTouch®, please contact your doctor or nurse.

Frequently asked questions

What does low blood sugar (hypoglycemia) mean?

Sometimes the blood sugar can drop too low. The blood sugar is too low when it is under 4.0 mmol/l. This is called hypoglycemia. Like all insulin products Tresiba® can cause hypoglycemia. You can minimize the risk of hypoglycemia by always following the guidelines that your doctor or nurse has given you.

Hypoglycemia means an abnormally low level of sugar in the blood. It is caused by too much insulin or other medication for diabetes. Blood sugar is too low when it is under 4.0 mmol/l. This is called hypoglycemia.

The blood sugar level can fall too low if:

- you take too much insulin
- you are more physically active than normally
- you drink alcohol
- you skip or delay a meal
- you eat too little

Low blood sugar can also be caused by other factors. Knowing your blood sugar level can help you decide how much medicine to take, what food to eat, and how physically active to be. Discuss with your doctor or nurse when you should check your blood sugar and how you can prevent and handle events of low blood sugar.

How do you know when your blood sugar is low?

The blood sugar level can drop very fast. Symptoms of hypoglycemia tend to come on quickly and can vary from person to person. You may have one or more mild-to-moderate symptoms listed in the table below. Sometimes people don't feel any symptoms.

Hypoglycemia symptoms are among others:

- Nausea, hunger, irritation, numbness or pain in the fingertips or lips, shakiness or dizziness, vision changes

Everyone reacts differently to low blood sugar. Your doctor or nurse can help you identify the symptoms and deal with hypoglycemia. Wear a medical bracelet or pendant that tells other people that you have diabetes in case your blood sugar drops too low.



What should you do when your blood sugar is too low?

- If you experience hypoglycaemia symptoms, take some quickly absorbed carbohydrates right away.
- Eat glucose tablets or other sugary snacks, such as juice, fruit or cookies (always carry glucose tablets or other sweets with you for safety's sake).
- Check your blood sugar if possible and rest. You may have to eat multiple times as it might take some time for the blood sugar to reach its normal levels. This is the case especially with all long-acting insulins.
- If hypoglycaemia results in unconsciousness, you will need help. The helper has to roll you onto your side with the head tilted back and call the ambulance immediately. An unconscious person should never be given something to eat or drink as he/she may suffocate.

Tell your family, friends and co-workers about hypoglycaemia and its symptoms in order for them to know how help you out when needed. Following your diabetes management plan set by your doctor or nurse will help you manage your blood sugar. Eating regular meals is key to prevent low blood sugar events. Remember to discuss with your doctor or nurse if you want to change your diet or your physical activity level.

Novo Nordisk is a global healthcare company with over 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs over 40.000 employees in 77 countries and markets its products in over 165 countries. In Finland, Novo Nordisk Farma Oy employs a staff of approximately 60.

Changing Diabetes® explains the ambition and commitment with which we develop our business and how we wish to be known as a company. It means that the goal behind our every decision and action is to improve the lives of people living with diabetes. We try to reach this goal by developing pharmaceutical treatments that are based on a deep understanding of the individual needs, hopes and views of diabetics. In our work, we respect the environment and carry our financial and social responsibility.

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