A guide for **adults/adolescents**

TRESIBA®
insulin degludec

Supporting you with your Tresiba® treatment

This booklet is intended for UK-based adults and adolescents who have been prescribed Tresiba® (insulin degludec)

Information on warnings and precautions for Tresiba® can be found on pages 6–9 of this booklet.
Information on possible side effects for Tresiba® can be found on pages 13–18 of this booklet.


This is not a real patient and is for illustrative purposes only.

Please refer to the Package Leaflet: Information for the patient found in the product carton for:

- Further information on Tresiba®
- Further information on how to use Tresiba®
- A full list of side effects, warnings and precautions

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0800 023 2573). Calls may be monitored for training purposes. By reporting side effects, you can help provide more information on the safety of this medicine.

novo nordisk®

This material has been produced and funded by Novo Nordisk for UK-based adult and adolescent patients who have already been prescribed Tresiba®. This information does not replace the Package Leaflet: Information for the patient, which you are advised to read in full. It is not intended as a substitute for clinical advice provided by your healthcare professional. Please contact your healthcare professional if you have any questions about your treatment and for clinical advice. This material is designed to be viewed digitally. It contains hyperlinks which are viewable online only.

This booklet has been made with you in mind, to help support you throughout your insulin treatment.

It will give you:

- Information about Tresiba®
- An explanation of how Tresiba® works
- Some things to remember when injecting your daily Tresiba® dose

If there are any words in this booklet that are new or difficult to understand, please look at the section at the back called '**Useful words to know**'.

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Contents

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Why have you been prescribed Tresiba®?

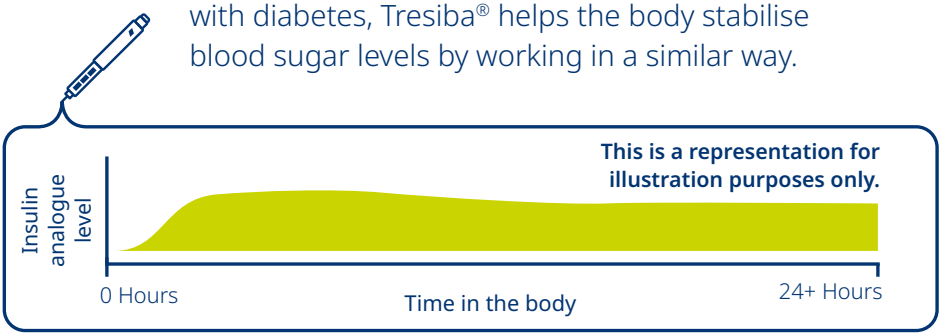
Having diabetes means that managing your blood sugar levels is very important.

You and your healthcare professional have decided that Tresiba®, also known as insulin degludec, is the appropriate kind of insulin to help you do this.

More information on what is covered in the rest of this booklet can be found in the **Package Leaflet: Information for the patient** enclosed with your product carton. Please take the time to read through this in full. If you still have any questions or queries, please speak with your healthcare professional.

How Tresiba® works

In people without diabetes, the body naturally releases insulin into the bloodstream. This helps control blood sugar levels and keeps them consistent throughout the day. In people with diabetes, Tresiba® helps the body stabilise blood sugar levels by working in a similar way.



Tresiba® is used for once-daily dosing and has a long blood sugar-lowering effect.

Tresiba® is a long-acting basal insulin that helps your body reduce your blood sugar level. Tresiba® works for longer than some other insulins, such as short- or intermediate-acting ones and can be used with meal-related rapid-acting insulin products. In type 2 diabetes, Tresiba® may be used in combination with tablets for diabetes or with injectable antidiabetic medicines, other than insulin. In type 1 diabetes, Tresiba® must always be used in combination with meal-related rapid-acting insulin medicines.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

What you need to know before you use Tresiba®

Please refer to the Package Leaflet: Information for the patient found in the product carton for a full list of warnings and precautions.

Do not use Tresiba®

- If you are allergic to insulin degludec or any of the other ingredients of this medicine
- If the cartridge or the delivery system you are using is damaged

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Tresiba®. Be especially aware of the following:

- Low blood sugar (hypoglycaemia) – if your blood sugar is too low
- High blood sugar (hyperglycaemia) – if your blood sugar is too high
- Switching from other insulin medicines – the insulin dose may need to be changed if you switch from another type, brand or manufacturer of insulin. Talk to your doctor
- Pioglitazone used together with insulin, see 'Pioglitazone' on page 8
- Eye disorder – fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disorder. If you experience eye problems, talk to your doctor
- Ensuring you use the right type of insulin – always check the insulin label before each injection to avoid accidental mix-ups between different

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

strengths of Tresiba® as well as other insulin products

If you have kidney or liver problems

If you have kidney or liver problems, you may need to check your blood sugar level more often. Talk to your healthcare professional about changes in your dose.

Skin changes at the injection site

The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Tell your doctor if you notice any skin changes at the injection site. Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medication's dose.

Children and adolescents

Tresiba® can be used in adolescents and children aged 1 year and above. There is no experience with the use of Tresiba® in children below the age of 1 year.

Other medicines and Tresiba®

Tell your doctor, pharmacist 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 change.

Listed on the next page are the most common medicines which may affect your insulin treatment.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

Your blood sugar level may fall (hypoglycaemia) if you take:

- Other medicines for diabetes (oral and injectable)
- Sulfonamides, for infections
- Anabolic steroids, such as testosterone
- Beta-blockers, for high blood pressure. They may make it harder to recognise the warning signs of too low blood sugar
- Acetylsalicylic acid (and other salicylates), for pain and mild fever
- Monoamine oxidase (MAO) inhibitors, for depression
- Angiotensin-converting enzyme (ACE) inhibitors, for some heart problems or high blood pressure

Your blood sugar level may rise (hyperglycaemia) if you take:

- Danazol, for endometriosis
- Oral contraceptives (birth control pills)
- Thyroid hormones, for thyroid problems
- Growth hormone, for growth hormone deficiency
- Glucocorticoids such as 'cortisone', for inflammation
- Sympathomimetics such as epinephrine (adrenaline), salbutamol or terbutaline, for asthma
- Thiazides, for high blood pressure or if your body keeps too much water (water retention)

Octreotide and lanreotide: used to treat a rare condition involving too much growth hormone (acromegaly). They may increase or decrease your blood sugar level.

Pioglitazone: oral antidiabetic medicine used to treat type 2 diabetes mellitus. Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone and insulin experienced the development of heart failure. Inform your doctor immediately if you experience signs of heart failure

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

such as unusual shortness of breath, rapid increase in weight or localised swelling (oedema).

If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse.

Tresiba® with alcohol

If you drink alcohol, your need for insulin may change. Your blood sugar level may either rise or fall. You should therefore monitor your blood sugar level more often than usual.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your insulin dose may need to be changed during pregnancy and after delivery. Careful control of your diabetes is needed in pregnancy. Avoiding too low blood sugar (hypoglycaemia) is particularly important for the health of your baby.

Driving and using machines

Having too low or too high blood sugar can affect your ability to drive or use any tools or machines. If your blood sugar is too low or too high, your ability to concentrate or react might be affected. This could be dangerous to yourself or others. Ask your doctor whether you can drive if:

- You often get too low blood sugar
- You find it hard to recognise too low blood sugar

Important information about some of the ingredients of Tresiba®

This medicine contains less than 1 mmol sodium (23 mg) per dose. This means that the medicine is essentially 'sodium-free'.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

How to use Tresiba®

You and your doctor will decide how much Tresiba® you will need each day, when to check your blood sugar levels, and if you need a higher or lower dose.

You will only need to inject Tresiba® **once a day**. It is best to inject it at the same time every day, so be sure to choose a time that works best for you.

Tips

Here are some tips that may help you remember when to inject your dose:

Set a reminder or alarm on your phone

Plan your dose alongside your daily routine

Tell a friend or member of your family when your dose should be and ask them to help remind you

It is important to make sure you inject your Tresiba® dose at the same time every day as part of your routine. However, on rare occasions where you cannot inject your dose at the same time, it can be injected at a different time of day ensuring a minimum of **8 hours** between the doses.

If you **forget to inject 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,

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

do not inject a double dose, but resume your once-daily dosing schedule. Please see page 18 of this booklet for more information on what to do if you get too high blood sugar.

If you **inject more Tresiba® than you should**, your blood sugar levels may get too low. Please see page 16 of this booklet on what to do if this happens.

Do not stop using your insulin without talking to your doctor. If you stop using your insulin, this could lead to a very high blood sugar level and ketoacidosis (a condition with too much acid in the blood).

Please refer to the Package Leaflet: Information for the patient with your product carton for a step-by-step visual guide on how to use/inject Tresiba®.

Before you use Tresiba® for the first time, your healthcare professional will show you how to use it. Always follow the injection guidance given by your doctor, nurse, or pharmacist. Please refer to 'Tips' on page 20 for more information.

Always use Tresiba® exactly as your doctor, nurse or pharmacist has told you to. If you are unsure, or have any questions, please check with them. Do not stop using insulin without talking to your doctor.

Things to do before injecting your dose

Before you inject your daily dose, there are some things which may be helpful for you to do and check:

Before you use Tresiba® for the first time, your doctor or nurse will show you how to use it

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

Remember to check the label to make sure you have the correct medication and the correct strength of Tresiba®. This is especially important if you take more than one type of insulin

Check the appearance of your insulin

- Tresiba® should be clear and colourless

Make sure you have your needles

- These are packed separately to your insulin

Always use a new needle for each injection to prevent contamination, infection and leakage of insulin. This will also prevent your needle becoming blocked, which could result in you receiving an incorrect dosage

Needles, syringes and pre-filled pens must not be shared

Things to remember when injecting your dose

Your Tresiba® dose is only given by an injection under the skin. The best places to inject are the front of your thighs, upper arms or the front of your waist (abdomen). Change the place within the area where you inject each day to reduce the risk of developing lumps and skin pitting. Being concerned about injections is normal. It is important to remember that you are not alone in this — many people are experiencing and feeling the same things.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

Possible side effects

Please refer to the Package Leaflet: Information for the patient found in the product carton for a full list of possible side effects.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Hypoglycaemia (too low blood sugar) may occur very commonly with insulin treatment (may affect more than 1 in 10 people). It can be very serious. If your blood sugar level falls too much, you may become unconscious. Serious hypoglycaemia may cause brain damage and may be life-threatening. If you have symptoms of low blood sugar, take actions to increase your blood sugar level immediately.

If you have a serious allergic reaction (seen rarely) to the insulin or any of the ingredients in Tresiba®, stop using this medicine and see a doctor straight away. The signs of a serious allergic reaction are:

- The local reactions spread to other parts of your body
- You suddenly feel unwell with sweating
- You start being sick (vomiting)
- You experience difficulty in breathing
- You experience rapid heartbeat or feeling dizzy

Skin changes at the injection site:

If you inject insulin at the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy) (may affect up to 1 in 100 people). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Change the injection site with each injection to help prevent these skin changes.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

Other side effects include:

Common (may affect up to 1 in 10 people)

Local reactions: local reactions at the place you inject yourself may occur. The signs may include: pain, redness, hives, swelling and itching. The reactions usually disappear after a few days. See your doctor if they do not disappear after a few weeks. Stop using Tresiba® and see a doctor straight away if the reactions become serious.

Uncommon (may affect up to 1 in 100 people)

Swelling around your joints: when you first start using your medicine, your body may keep more water than it should. This causes swelling around your ankles and other joints. This is usually only short-lasting.

Rare (may affect up to 1 in 1,000 people)

This medicine can cause allergic reactions such as hives, swelling of the tongue and lips, diarrhoea, nausea, tiredness and itching.

General effects from diabetes treatment

Too low blood sugar (hypoglycaemia)

Too low blood sugar may happen if you:
drink alcohol; use too much insulin; exercise more than usual; eat too little or miss a meal.

Patient organisations, such as Diabetes UK, often have helpful information that can support you.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

Warning signs of too low blood sugar – these may come on suddenly:


Headaches


Slurred speech


Fast heartbeat


Cold sweats


Cool, pale skin


Feeling sleepy


Feeling sick (nausea)


Feeling very hungry


Feeling unusually tired or weak


Tremors or feeling nervous, or worried


Difficulty concentrating or feeling confused


Short-lasting changes in vision

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

What to do if you get too low blood sugar

- Eat glucose tablets or another high sugar snack, like sweets, biscuits or fruit juice (always carry glucose tablets or a high sugar snack, just in case)

- Measure your blood sugar if possible and rest. You may need to measure your blood sugar more than once, as with all basal insulin products improvement from the period of low blood sugar may be delayed

- Wait until the signs of too low blood sugar have gone or when your blood sugar level has settled. Then carry on with your insulin as usual

What others need to do if you pass out

Tell everyone you spend time with that you have diabetes. Tell them what could happen if your blood sugar gets too low, including the risk of passing out.

Let them know that if you pass out, they must:

- Turn you on your side
- Get medical help straight away
- **Not** give you any food or drink because you may choke

You may recover more quickly from passing out with an injection of glucagon. This can only be given by someone who knows how to use it.

- If you are given glucagon, you will need sugar or a sugary snack as soon as you come round
- If you do not respond to a glucagon injection, you will have to be treated in a hospital

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

- If severe low blood sugar is not treated over time, it can cause brain damage. This can be short- or long-lasting. It may even cause death

Talk to your doctor if:

- Your blood sugar got so low that you passed out
- You have used an injection of glucagon
- You have had too low blood sugar a few times recently

This is because the dosing or timing of your insulin injections, food or exercise may need to be changed.

Too high blood sugar (hyperglycaemia)

Too high blood sugar may happen if you:
eat more or exercise less than usual; drink alcohol; get an infection or a fever; have not used enough insulin; keep using less insulin than you need; forget to use your insulin or stop using insulin without talking to your doctor.

Warning signs of too high blood sugar – these normally appear gradually:


Flushed skin


Dry skin


Feeling drowsy or tired


Dry mouth


A fruity smell of the breath (acetone)

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

Increased urination

Feeling thirsty

Losing your appetite

Feeling or being sick (nausea or vomiting)

These may be signs of a very serious condition called ketoacidosis. This is a build-up of acid in the blood because the body is breaking down fat instead of sugar. If not treated, this could lead to diabetic coma and eventually death.

What to do if you get too high blood sugar

- Test your blood sugar level
- Test your urine or blood for ketones
- Get medical help straight away

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at https://yellowcard.mhra.gov.uk/↗ or search for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0800 023 2573). Calls may be monitored for training purposes. By reporting side effects, you can help provide more information on the safety of this medicine.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

Storage

- Make sure your Tresiba® insulin is kept out of the sight and reach of children
- Do not use your insulin after its expiry date, which is stated on the pen label and carton, after 'EXP'. The expiry date refers to the last day of that month
- Keep your insulin in the fridge at 2°C to 8°C until first use. Keep it away from the freezing element
- Do not freeze your insulin
- Depending on your injecting device, you may not need to keep your insulin in the fridge after the first use. Please refer to your Package Leaflet: Information for the patient enclosed with your insulin for specific storage instructions, including how to protect it from light before and after first opening

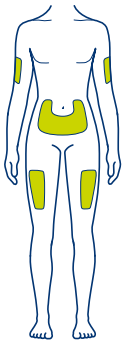
Always dispose of the needle immediately after each injection using a sharps bin. Never store your pen with the needle attached. Keep your sharps bin in a safe place so it's not a risk to other people and is out of the sight and reach of children. Sharps bins must not be disposed of in household waste. Discuss with your healthcare professional the procedure for disposing of sharps bins in your area.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

Tips

Here are some things to remember when injecting your dose:

- When injecting under the skin, make sure there is no air trapped in the needle. Please see your injectable device instructions for more information
- Do not inject directly into a vein or muscle
- Your healthcare professional will have advised you on the best places to inject your insulin. These can be the front of your thighs, upper arms, or the front of your waist (abdomen)
- Remember to change the place within the area where you inject each day. This can help reduce the chance of developing lumps and indentations under the skin
- Tell your healthcare professional if you notice any skin changes



When injecting your dose:

- Insert the needle into your skin as described by your doctor or nurse. Be sure you can see the dose counter when doing this
- Press and hold down the dose button, watching as the dose counter returns to 0
- Continue to press the dose button while keeping the needle under your skin for at least 6 seconds
- After 6 seconds, remove the needle from your skin and release the dose button

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Tresiba®.

Useful words to know

Term	Description
Basal insulin	A basal insulin is long-acting, unlike a bolus insulin, which is fast-acting. This means basal insulins help keep your blood glucose levels consistent throughout the day.
Blood glucose	The measurement of how much glucose is in your blood.
Glucose	The main type of sugar in the blood. It is also the major energy source for the body.
Hyperglycaemia	When your blood glucose levels are too high.
Hypoglycaemia	When your blood glucose levels are too low (below 4 mmol/l).
Insulin	A hormone produced by an organ in the body called the pancreas. It helps regulate the amount of glucose in your blood.
Lipoatrophy	If you inject insulin at the same place, loss of fat under the skin may occur, resulting in small dents. It can be avoided by rotating the injection site.
Lipohypertrophy	If you inject insulin at the same place, a build-up of fat below the surface of the skin may occur, causing lumps. This can be avoided by rotating the injection site.

If you need more information

If you have any questions or need anything explaining further, please contact your doctor, nurse or local pharmacist. They will be able to support you with any queries you may have and, if necessary, advise you on who to contact for more information.

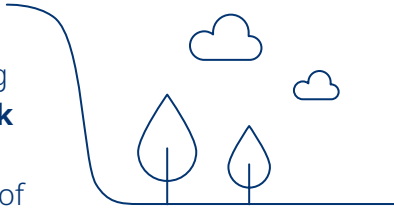
www.novonordisk.co.uk
Novo Nordisk have been working in diabetes since 1923. To find out more about our work, please visit our website.

circular FOR zero

We are adopting a circular mindset, designing products that can be recycled or re-used, reshaping our business to minimise consumption and waste, and working with suppliers who share our ambition. We call this Circular for Zero.

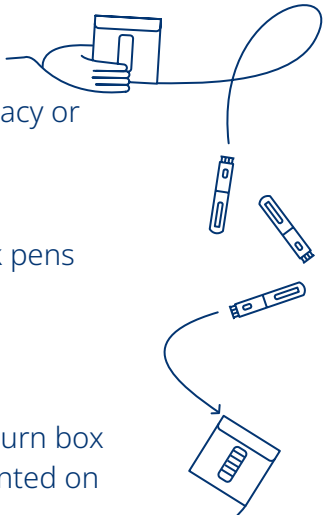
If you have been prescribed Tresiba® using a pre-filled pen you can now recycle your pens with PenCycle®.

What is PenCycle®?



PenCycle® is a free of charge, simple recycling programme for used **pre-filled Novo Nordisk** pens. By finding new ways to re-use them, we can help put an end to the unsustainable use of Earth's natural resources.

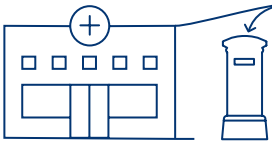
How can I **PenCycle®?**



1. Get a PenCycle® return box
Pick one up from a participating pharmacy or order online at www.pen-cycle.co.uk/

2. Fill it up
Place your used pre-filled Novo Nordisk pens inside the box

3. Send it back
Drop your full box at any participating pharmacy or return it by post (every return box has a FREEPOST Royal Mail barcode printed on the back)



You return it
We recycle it

Scan the QR code or visit www.pen-cycle.co.uk/ for full details and to find your nearest participating pharmacy.

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