A guide for **parents/carers**

TRESIBA®
insulin degludec

Supporting you with your child's Tresiba® treatment

This booklet is intended for UK-based parents/ carers whose child has been prescribed Tresiba® (insulin degludec)

Information on warnings and precautions for Tresiba® can be found on pages 6–8 of this booklet.
Information on possible side effects for Tresiba® can be found on pages 12–17 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 enclosed with your child's insulin for:

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

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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.

This material has been produced and funded by Novo Nordisk for UK-based parents/carers whose child has 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 child's healthcare professional. Please contact your child's healthcare professional if you have any questions about your child's 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, a parent/ carer of a child who has been prescribed Tresiba®, in mind, to help support you throughout their treatment.

It will give you:

- Information about Tresiba®
- An explanation of how Tresiba® works
- Some things to remember when injecting your child's 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**'.

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

Contents

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Why has my child been prescribed Tresiba®?

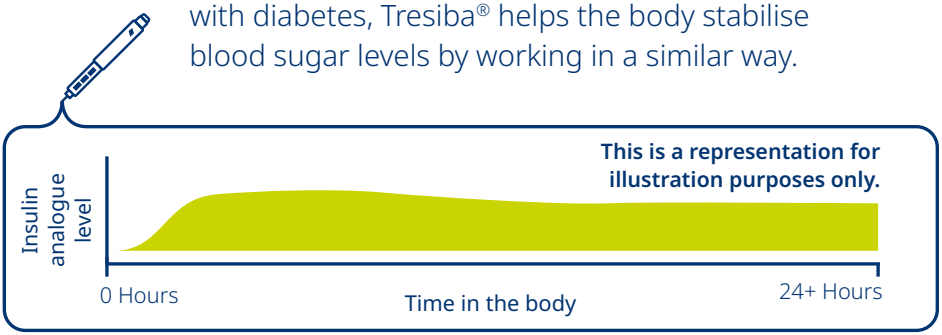
Managing your child's blood sugar levels is a very important part of keeping their diabetes under control.

You and your child's 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 child's insulin. Please take the time to read through this in full. If you still have any questions or queries, please speak with your child's 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 the body reduce blood sugar levels. 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 (much less common in children and young people), Tresiba® may be used in combination with tablets for diabetes or with injectable antidiabetic medicines, other than insulin. In type 1 diabetes (the most common form in children and young people), Tresiba® must always be used in combination with meal-related rapid-acting insulin medicines.

Please refer to the Package Leaflet: Information for the patient enclosed with your child's insulin in full for further information on Tresiba®.

What you need to know before using Tresiba®

Please refer to the Package Leaflet: Information for the patient enclosed with your child's insulin for a full list of warnings and precautions.

Do not use Tresiba®

- If your child is 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 child's doctor, pharmacist or nurse before using Tresiba®. Be especially aware of the following:

- Low blood sugar (hypoglycaemia) – if your child's blood sugar is too low
- High blood sugar (hyperglycaemia) – if your child's blood sugar is too high
- Switching from other insulin medicines – the insulin dose may need to be changed if your child switches from another type, brand or manufacturer of insulin. Talk to your child's doctor
- Eye disorder – fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disorder. If your child experiences eye problems, talk to your child's doctor
- Ensuring your child uses 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

Please refer to the Package Leaflet: Information for the patient enclosed with your child's insulin in full for further information on Tresiba®.

If your child has kidney or liver problems

If your child has kidney or liver problems, you may need to check your child's blood sugar level more often. Talk to your child's healthcare professional about changes in their 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 child's doctor if you notice any skin changes at the injection site. Tell your child's doctor if you are currently injecting into these affected areas before you start injecting in a different area. Your child's doctor may tell you to check your child's blood sugar more closely, and to adjust your child's insulin or their 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 child's doctor, pharmacist or nurse if they are taking, have recently taken or might take any other medicines. Some medicines affect your child's blood sugar level – this may mean their insulin dose has to change.

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

Please refer to the Package Leaflet: Information for the patient enclosed with your child's insulin in full for further information on Tresiba®.

Your child's blood sugar level may fall (hypoglycaemia) if they 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 child's blood sugar level may rise (hyperglycaemia) if they 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 the 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 child's blood sugar level.

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 enclosed with your child's insulin in full for further information on Tresiba®.

How to use Tresiba®

You and your child's doctor will decide how much Tresiba® your child will need each day, when to check your child's blood sugar levels, and if your child needs 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 and your child.

Tips

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

Set a reminder or alarm on your phone

Plan your child's dose alongside their daily routine

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

It is important to make sure you inject your child's Tresiba® dose at the same time every day as part of their routine. However, on rare occasions where you cannot inject your child's 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 child's previous dose when it is time to give your child's next regular scheduled dose,

Please refer to the Package Leaflet: Information for the patient enclosed with your child's insulin in full for further information on Tresiba®.

do not inject a double dose, but resume your child's once-daily dosing schedule. Please see page 17 of this booklet for more information on what to do if your child gets too high blood sugar.

If you **inject more Tresiba® than you should**, your child's blood sugar levels may get too low. Please see page 15 of this booklet on what to do if this happens.

Do not stop using Tresiba® without talking to your child's doctor. If your child stops using 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 enclosed with your child's insulin for a step-by-step visual guide on how to use/inject Tresiba®.

Before using Tresiba® for the first time, your child's healthcare professional will show you how to use it. Always follow the injection guidance given by your child's doctor, nurse, or pharmacist. Please refer to 'Tips' on page 19 for more information.

Always use Tresiba® exactly as your child's 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 child's doctor.

Things to do before injecting your child's dose

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

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

Please refer to the Package Leaflet: Information for the patient enclosed with your child's insulin 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 your child takes more than one type of insulin

Check the appearance of your child's insulin

- Tresiba® should be clear and colourless

Make sure you have your child's needles

- These are packed separately to their insulin

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

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

Things to remember when injecting your child's dose

Your child's Tresiba® dose is only given by an injection under the skin. The best places to inject are the front of their thighs, upper arms or the front of their 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 your child is not alone in this — many people are experiencing and feeling the same things.

Please refer to the Package Leaflet: Information for the patient enclosed with your child's insulin in full for further information on Tresiba®.

Possible side effects

Please refer to the Package Leaflet: Information for the patient 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 child's blood sugar level falls too much, they may become unconscious. Serious hypoglycaemia may cause brain damage and may be life-threatening. If your child has symptoms of low blood sugar, take actions to increase their blood sugar level immediately.

If your child has 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 child's body
- Your child suddenly feels unwell with sweating
- Your child starts being sick (vomiting)
- Your child experiences difficulty in breathing
- Your child experiences 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 enclosed with your child's insulin 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 your child may occur. The signs may include: pain, redness, hives, swelling and itching. The reactions usually disappear after a few days. See your child's 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 child's joints: when your child first starts using their medicine, their body may keep more water than it should. This causes swelling around their 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 your child: uses too much insulin; exercises more than usual; eats too little or misses 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 enclosed with your child's insulin 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 enclosed with your child's insulin in full for further information on Tresiba®.

What to do if your child gets 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 child's blood sugar if possible and get them to rest. You may need to measure their 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 child's blood sugar level has settled. Then carry on with your child's insulin as usual

What you or others need to do if your child passes out

Tell everyone your child spends time with that they have diabetes. Tell them what could happen if your child's blood sugar gets too low, including the risk of passing out.

Let them know that if your child passes out, they must:

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

Your child 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 your child is given glucagon, they will need sugar or a sugary snack as soon as they come round
- If your child does not respond to a glucagon injection, they will have to be treated in a hospital

Please refer to the Package Leaflet: Information for the patient enclosed with your child's insulin 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 child's doctor if:

- Your child's blood sugar got so low that they passed out
- Your child has been given an injection of glucagon
- Your child has had too low blood sugar a few times recently

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

Too high blood sugar (hyperglycaemia)

Too high blood sugar may happen if your child: eats more or exercises less than usual; gets an infection or a fever; has not used enough insulin; keeps using less insulin than they need; forgets to use their insulin or stops using insulin without talking to a 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 enclosed with your child's insulin 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 your child gets too high blood sugar

- Test your child's blood sugar level
- Test your child's 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 enclosed with your child's insulin in full for further information on Tresiba®.

Storage

- Make sure your child's Tresiba® insulin is kept out of the sight and reach of children
- Do not use your child's 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 child's insulin in the fridge at 2°C to 8°C until first use. Keep it away from the freezing element
- Do not freeze your child's insulin
- Depending on your child's injecting device, you may not need to keep their insulin in the fridge after the first use. Please refer to the Package Leaflet: Information for the patient enclosed with your child's insulin for specific storage instructions, including how to protect it from light before and after first opening

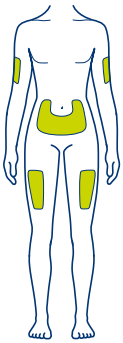
Always dispose of the needle immediately after each injection using a sharps bin. Never store your pen with the needle attached. Keep your sharps bin in a safe place so it's not a risk to other people and is out of the sight and reach of children. Sharps bins must not be disposed of in household waste. 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 enclosed with your child's insulin in full for further information on Tresiba®.

Tips

Here are some things to remember when injecting your child's dose:

- When injecting under the skin, make sure there is no air trapped in the needle. Please see your child's injectable device instructions for more information
- Do not inject directly into a vein or muscle
- Your child's healthcare professional will have advised you on the best places to inject your child's insulin. These can be the front of their thighs, upper arms, or the front of their 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 child's healthcare professional if you notice any skin changes



When injecting your child's dose:

- Insert the needle into your child's skin as described by your child's 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 child's skin for at least 6 seconds
- After 6 seconds, remove the needle from your child's skin and release the dose button

Please refer to the Package Leaflet: Information for the patient enclosed with your child's insulin 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.

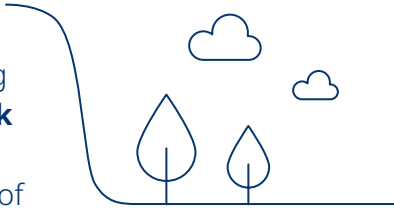
www.novonordisk.co.uk
Novo Nordisk have been working in diabetes since 1923. To find out more about our work, please visit our website.

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 your child has been prescribed Tresiba® using a pre-filled pen you can now recycle their pens with PenCycle®.

What is PenCycle®?



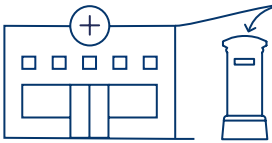
PenCycle® is a free of charge, simple recycling programme for used **pre-filled Novo Nordisk** pens. By finding new ways to re-use them, we can help put an end to the unsustainable use of Earth's natural resources.

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 child's 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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