

**Package leaflet: Information for the patient**  
**Tresiba® 100 units/mL solution for injection in cartridge**  
(insulin degludec)

Your medicine is known as the above but will be referred to as Tresiba throughout the remainder of this leaflet.

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Tresiba is and what it is used for
2. What you need to know before you use Tresiba
3. How to use Tresiba
4. Possible side effects
5. How to store Tresiba
6. Contents of the pack and other information

**1. What Tresiba is and what it is used for**

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. Tresiba helps your body reduce your blood sugar level. It is used for once-daily dosing. On occasions when you cannot follow your regular dosing schedule, you can change the time of dosing because Tresiba has a long blood sugar-lowering effect (see section 3 for 'Flexibility in dosing time'). Tresiba can be used with meal-related rapid-acting insulin products. In type 2 diabetes mellitus, Tresiba may be used in combination with tablets for diabetes or with injectable antidiabetic medicines, other than insulin. In type 1 diabetes mellitus, Tresiba must always be used in combination with meal-related rapid-acting insulin medicines.

**2. What you need to know before you use Tresiba**

**Do not use Tresiba**

- ▶ if you are allergic to insulin degludec or any of the other ingredients of this medicine (listed in section 6).

**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, follow the guidance for low blood sugar in section 4.
- High blood sugar (hyperglycaemia) – if your blood sugar is too high, follow the guidance for high blood sugar in section 4.
- 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' below.
- 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 Tresiba and other insulin products.

If you have poor eyesight, please see section 3.

**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 (see section 3 'How to use Tresiba'). 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 medications 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 be changed.

Listed below are the most common medicines which may affect your insulin treatment.

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 (see section 4 '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 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'.

**3. How to use Tresiba**

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this insulin product without help. Get help from a person with good eyesight who is trained to use the pen.

**Your doctor will decide together with you:**

- how much Tresiba you will need each day
- when to check your blood sugar level and if you need a higher or lower dose.

**Flexibility in dosing time**

- Always follow your doctor's recommendation for dose.
- Use Tresiba once each day, preferably at the same time every day.
- 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 between the doses. There is no experience with flexibility in dosing time of Tresiba in children and adolescents.
- If you want to change your usual diet, check with your doctor, pharmacist or nurse first as a change in diet may alter your need for insulin.

Based on your blood sugar level, your doctor may change your dose.

When using other medicines, ask your doctor if your treatment needs to be adjusted.

**Use in elderly (≥65 years old)**

Tresiba can be used in elderly, but if you are elderly, you may need to check your blood sugar level more often. Talk to your doctor about changes in your dose.

**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 doctor about changes in your dose.

**Injecting your medicine**

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

- ▶ Please also read the manual that comes with your insulin delivery system.
- ▶ Check the name and strength on the label to make sure it is Tresiba 100 units/mL.

**Do not use Tresiba**

- ▶ in insulin infusion pumps.
- ▶ if the cartridge or the delivery system you are using is damaged. Take it back to your supplier. See your delivery system manual for further instructions.
- ▶ if the cartridge is damaged or has not been stored correctly (see section 5 'How to store Tresiba').
- ▶ if the insulin does not appear clear and colourless.

**How to inject**

- ▶ Tresiba is given as an injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.
- ▶ 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 (see section 4).
- ▶ Always use a new needle for each injection. Re-use of needles may increase the risk of blocked needles leading to inaccurate dosing. Dispose of the needle safely after each use.