Package leaflet: Information for the patient

Tresiba® 100 units/mL **Solution for injection in cartridge**
insulin degludec

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

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
It is not known if Tresiba® affects the baby in pregnancy or during 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.

If you use more Tresiba® than you should
If you use too much insulin, your blood sugar may get too low (hypoglycaemia), see advice in section 4 'Too low blood sugar'.

If you forget to use Tresiba®
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.

If you stop using Tresiba®
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), see advice in section 4 'Too high blood sugar'.

4. 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. See advice in 'Too low blood sugar' below.

If you have a serious allergic reaction (seen rarely) to the insulin or any of the ingredients in Tresiba®, stop using Tresiba® 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.

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. For more information, see 'serious allergic reaction' above.

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.

Warning signs of too low blood sugar – these may come on suddenly:
Headache; slurred speech; fast heartbeat; cold sweat, cool pale skin; feeling sick, feeling very hungry; tremor or feeling nervous or worried; feeling unusually tired, weak and sleepy; feeling confused, difficulty in concentrating; short-lasting changes in your sight.

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.
- 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, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, 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 this leaflet. You can also report side effects directly via

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. 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 Penfill® label and carton, after 'EXP'. The expiry date refers to the last day of that month.

Before first use
Store 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
Do not refrigerate. You can carry your Tresiba® cartridge (Penfill®) with you and keep it at room temperature (not above 30°C) for up to 8 weeks.

Always keep Tresiba® Penfill® in the outer carton when you are not using it in order to protect it from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tresiba® contains

- The active substance is insulin degludec. Each mL of solution contains 100 units of insulin degludec. Each cartridge contains 300 units of insulin degludec of insulin in 3 ml solution.
- The other ingredients are glycerol, metacresol, phenol, zinc acetate, hydrochloric acid and sodium hydroxide (for pH adjustment) and water for injections (see section 2).

What Tresiba® looks like and contents of the pack
Tresiba® is presented as a clear and colourless solution for injection in a cartridge (300 units per 3 mL).

Pack sizes of 5 and 10 cartridges of 3 mL. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd, Denmark

This leaflet was last revised in 09/2020

Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu