

Tresiba® Penfill®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Tresiba®?

Tresiba® contains the active ingredient insulin degludec. Tresiba® is used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above.

For more information, see Section [1. Why am I using Tresiba®?](#) in the full CMI.

2. What should I know before I use Tresiba® ?

Do not use if you have ever had an allergic reaction to insulin degludec or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions or take any other medicines. For more information, see Section [2. What should I know before I use Tresiba®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tresiba® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Tresiba® Penfill®?

- Tresiba® Penfill® is a pre-filled glass cartridge designed to be used with Novo Nordisk insulin delivery devices such as NovoPen® and NovoFine® needles.
- Use Tresiba® once each day, preferably at the same time each day.
- Your doctor or diabetes education nurse will decide with you how much Tresiba® you will need each day
- Your doctor, diabetes education nurse or pharmacist will have given you advice on how to use your medicine. Carefully follow all the directions.

More instructions can be found in Section [4. How do I use Tresiba®?](#) in the full CMI.

5. What should I know while using Tresiba®?

| | |
|----------------------------------|--|
| Things you should do | <ul style="list-style-type: none"> • Remind any doctor, nurse, dentist or pharmacist you visit that you are using Tresiba®. • Monitor your condition and know how to identify and manage 'Too low blood sugar' and 'Too high blood sugar'. |
| Things you should not do | <ul style="list-style-type: none"> • Do not use stop using Tresiba® unless your doctor tells you to. • Do not use if the solution is not clear and colourless. |
| Driving or using machines | <ul style="list-style-type: none"> • 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. |
| Drinking alcohol | <ul style="list-style-type: none"> • If you drink alcohol, the amount of insulin you need may change. Your blood sugar level may either rise or fall. |

| | |
|------------------------------------|---|
| | This means you need to check your blood sugar level more often than usual. |
| Looking after your medicine | <ul style="list-style-type: none"> • Before first use: Store in a refrigerator (2°C to 8°C). • After first opening or if carried as a spare: You can carry it with you and keep it at room temperature (below 30 °C) for up to 28 days. Discard any remaining after 28 days. • Do not freeze. Keep away from the freezing element. |

For more information, see Section [5. What should I know while using Tresiba®?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include injection site reactions and swelling from water retention after starting treatment. Serious side effects may include low blood sugar (hypoglycaemia or 'hypo') or an allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Tresiba® Penfill®

Active ingredient: *insulin degludec*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tresiba®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tresiba®.**

Where to find information in this leaflet:

- [1. Why am I using Tresiba®?](#)
- [2. What should I know before I use Tresiba®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Tresiba® Penfill®?](#)
- [5. What should I know while using Tresiba® ?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Tresiba®?

Tresiba® contains the active ingredient insulin degludec. Tresiba® is a modified insulin, also called an insulin analogue, which is similar to the insulin produced by the pancreas.

Tresiba® is used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above.

Diabetes mellitus is a condition in which your pancreas does not produce enough insulin to control your blood sugar (glucose) level. Extra insulin is therefore needed.

There are two types of diabetes mellitus:

- Type 1 diabetes
- Type 2 diabetes

Patients with type 1 diabetes always require insulin to control their blood sugar levels.

Some patients with type 2 diabetes may also require insulin after initial treatment with diet, exercise and tablets.

Tresiba® should be used once a day, preferably at the same time every day. It may be used in combination with diabetes tablets, or with a meal-related short- or rapid-acting insulin, such as NovoRapid®, or with other injectable diabetes medicines.

As with all insulin, the duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity.

Ask your doctor, diabetes education nurse or pharmacist if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I use Tresiba®?

Warnings

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

Do not use Tresiba® if:

- **you are allergic to any medicine containing insulin, or any of the ingredients listed at the end of this leaflet.**

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include: redness, swelling, rash and itching at the injection site, rash, itching or hives on the skin, shortness of breath, wheezing or difficulty breathing swelling of the face, lips, tongue or other parts of the body.

- **you are experiencing low blood sugar levels (a "hypo") when your dose is due.** If you have a lot of hypos discuss appropriate treatment with your doctor.

Check with your doctor if you:

- have any other medical conditions such as kidney or liver problems, adrenal, pituitary or thyroid gland problems, heart disease or stroke
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Pregnancy may make managing your diabetes more difficult. Insulin needs usually decrease during the first three months of pregnancy and increase during the last six months. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risk and benefits involved.

Children

Do not give this medicine to children aged less than 1 year.

The safety and efficacy of Tresiba® in children below 1 year of age has not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Tresiba® may interfere with each other.

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

- other medicines to treat diabetes, including oral hypoglycaemic medicines - used to treat type 2 diabetes
- sulfonamides – used to treat bacterial infections
- anabolic steroids – used to promote growth
- non-selective beta-blockers – used to treat high blood pressure and certain heart conditions
- salicylates e.g. aspirin – used to relieve pain and lower fever
- monoamine oxidase inhibitors (MAOI) – used for the treatment of depression
- alpha blockers - used to treat high blood pressure and to relieve difficulty in passing urine caused by an enlarged prostate

- angiotensin converting enzyme (ACE) inhibitors
– used to treat high blood pressure, certain heart conditions or elevated protein/albumin in the urine
- quinine - used to treat malaria and relieve muscle cramps
- quinidine - used to treat heart problems.

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

- danazol – used to treat endometriosis, menorrhagia, fibrocystic breast disease and hereditary angioedema
- oral contraceptives – used for birth control ("the pill")
- thyroid hormones – used to treat malfunction of the thyroid gland
- growth hormone – used to treat growth disorder
- glucocorticoids (except when applied locally) – used to treat inflammatory conditions
- sympathomimetics – such as adrenaline, salbutamol or terbutaline, for asthma
- diuretics e.g. thiazides, frusemide or ethacrynic acid
– used to treat high blood pressure or fluid retention (oedema)
- sympathomimetics - adrenaline and medicines used to treat asthma, such as salbutamol or terbutaline
- oxymetholone - used to treat certain blood disorders
- diazoxide - used to treat high blood pressure
- nicotinic acid - used to treat high cholesterol levels in the blood
- asparaginase - used to treat leukaemia and lymph gland tumours.

Other medicines may either increase or decrease your blood sugar level, including:

- octreotide - used to treat gastrointestinal endocrine tumours and enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- lanreotide - used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels

Beta-blockers may make it harder to recognise the warning signs of too low blood sugar (hypoglycaemia).

Thiazolidinediones – some patients with long-standing type 2 diabetes and heart disease, or previous stroke, treated with thiazolidinediones in combination with insulin experienced the development of symptoms of heart failure. Tell your doctor straight away if you have signs of heart failure such as shortness of breath, tiredness, fluid retention, rapid weight gain and ankle swelling.

Check with your doctor, pharmacist or nurse if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tresiba®.

4. How do I use Tresiba® Penfill®?

Your doctor, diabetes education nurse or pharmacist will have given you advice on how to use your medicine. Carefully follow all the directions.

They may differ from the information contained in this leaflet.

If you are blind or have poor eyesight and cannot read the dose counter on your insulin delivery device, get help from a person with good eyesight who is trained to use the device.

Any change in dose or type of insulin should be made cautiously and only under medical supervision.

If you change the type of insulin that you use, you may have to use more or less than before. This may happen with the first dose or over a period of time.

If you do not understand the instructions, ask your doctor, diabetes education nurse or pharmacist for help.

How much to take

Your doctor or diabetes education nurse will decide 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

It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

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

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

When to use Tresiba®

Use Tresiba® once each day, preferably at the same time each day. However, if you are unable to take Tresiba® at the regular scheduled time or forget to take a dose, then you can take it upon discovery and then resume your usual once a day schedule provided a minimum of 8 hours has passed between injections.

How to use Tresiba® Penfill®

- Tresiba® Penfill® is a pre-filled 3mL glass cartridge designed to be used with Novo Nordisk insulin delivery devices such as NovoPen® and NovoFine® needles.
- Carefully follow the instructions on how to use your Novo Nordisk insulin delivery device.
- Do not use the insulin level indicator on the insulin delivery device to measure your dose of Tresiba®.
- If you use Tresiba® Penfill® and another type of Penfill® (another type of insulin), you must use a separate insulin delivery device for each type of Penfill®.
- Take care not to drop or knock the insulin delivery device that contains Tresiba® Penfill®.
- As a precautionary measure, always carry a spare Penfill® in case your in-use Penfill® is lost or damaged.
- You should inject Tresiba® under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse. **Never inject Tresiba® directly into a vein or muscle.**

- Tresiba® may be injected into your abdomen, thigh or upper arm.
- Remember to change your injection site regularly as shown to you by your doctor or diabetes education nurse.
- Always use a new needle for each injection to avoid contamination. Needles must not be shared.
- When Tresiba® is used by children or adolescents, it is important to select the needle length appropriate for use in these patients.
- Do not use Tresiba® in insulin pumps.

Check your Tresiba® Penfill®:

Check your Tresiba® Penfill® before each preparation and injection. Check the name and strength on the label to make sure you are using the correct type of insulin.

Do not use if the solution does not appear clear and colourless. Do not use this medicine if it is thickened, coloured, or has solid bits in it.

Always check the cartridge, including the rubber plunger (stopper). Do not use it if any damage is seen or if there is a gap between the plunger and the white label band.

If you note any of the above, return your Penfill® to your pharmacist – **do not use your Penfill®.**

Preparing a dose:

1. Wash your hands.
2. If Penfill® is already inside your insulin delivery device, check the amount of insulin remaining. If there is

insufficient insulin for your dose, follow the relevant instructions in the device user manual.

3. Alternatively, or if your insulin delivery device does not already carry a Penfill® cartridge, load a new Tresiba® Penfill®.
4. Disinfect the rubber membrane of Penfill® with an alcohol swab.
5. Attach a NovoFine® needle.

Checking for insulin flow (priming):

Always check your Novo Nordisk insulin delivery device for insulin flow (priming) before each injection, as described in the device user manual.

The priming procedure may highlight a malfunction with your insulin delivery device. Priming also removes any air bubbles and helps indicate whether or not a needle is broken.

Only dial up your required dose after you see a drop of insulin at the needle tip.

After priming, if you need to put the insulin delivery device down, make sure the needle does not touch anything.

Injecting a dose:

Choose a site for injection.

Inject the medicine into the abdomen, thigh or upper arm.

Change the injection site regularly as shown to you by your doctor or diabetes education nurse.

This will reduce the chance of local skin reactions developing.

Pinch the skin between two fingers, push the needle into the raised skin, and inject the full dose of insulin under the skin.

Slowly count to 6 before pulling the needle out.

Apply gentle pressure over the injection site for several seconds.

Do not rub the area.

After injecting:

Using the outer needle cap, remove the used needle and dispose of it safely into a yellow plastic sharps container.

If you do not remove it, temperature changes may cause liquid to leak out of the needle.

Health care professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles, to eliminate the risk of needlestick injury.

Do not share needles, cartridges or pens.

Leave Penfill® in the insulin delivery device until it needs to be replaced.

How long to use Tresiba®

Do not stop using Tresiba® unless your doctor tells you to.

If you use too much Tresiba® (overdose) - Hypoglycaemia

If you think that you have used too much Tresiba®, your blood sugar may get too low (hypoglycaemia) - see advice in '[Too low blood sugar](#)'.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you forget to use Tresiba® - Hyperglycaemia

If you forget your insulin dose, check your blood sugar level and test your urine for ketones as soon as possible.

If you are not sure what to do, talk to your doctor, diabetes education nurse or pharmacist.

Do not take a double dose to make up for the dose you missed.

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using Tresiba® once a day with a minimum of 8 hours between doses.

5. What should I know while using Tresiba®?

Things you should do

Measure your blood sugar level regularly.

Make sure all friends, relatives, workmates, teachers and carers know that you have diabetes and are using insulin.

Keep using your insulin even if you feel well. It helps to control your condition, but does not cure it.

Tell your doctor if you often have hypos (low blood sugar levels). Your doctor may need to adjust your insulin dose.

Always carry some sugary food or fruit juice with you. If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice.

Tell your doctor if you have trouble recognising the symptoms of hypos. Under certain conditions, the early warning signs of hypos can be different or less obvious. Your doctor may need to adjust your insulin dose.

Tell your doctor if you notice any 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 medications dose.

Tell your doctor if you are ill. Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an insulin plan for those times when you are sick.

Tell your doctor if you are exercising more than usual. Exercise may lower your need for this medicine. Exercise may also speed up the effect of a dose of it, especially if the exercise involves the area of the injection site (e.g. the leg should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes. Changes in diet may cause your insulin needs to change.

Tell your doctor if you are having trouble with your eyesight. Visual disturbances in uncontrolled diabetes are reversed during the early stages of treatment.

Once established on insulin, if your vision changes, see your doctor as soon as possible.

Make sure that you tell every doctor, dentist, pharmacist or other health care professional who is treating you that you have diabetes and are using insulin.

Tell your doctor, diabetes education nurse or pharmacist if you are travelling. Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may need to inject your insulin and eat your meals at different times because of time differences in and between countries.

You may not be able to get the same type of insulin in the country you are visiting. Your doctor, diabetes education nurse or pharmacist can provide you with some helpful information.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Tresiba®.

Call your doctor straight away if:

- your blood sugar got so low that you passed out
- you have used glucagon
- you have had too low blood sugar a few times recently

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

Remind any doctor, nurse, dentist or pharmacist you visit that you are using Tresiba®.

Things you should not do

Do not stop using your Tresiba® 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 [‘Too high blood sugar’](#).

If you are blind or have poor eyesight and cannot read the dose counter on your insulin delivery device, get help from a person with good eyesight who is trained to use the device.

Do not use this medicine if you think it has been frozen or exposed to excessive heat.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not refill your Tresiba® Penfill®.

Do not share needles.

General effects from diabetes treatment

Too low blood sugar (hypoglycaemia)

This may happen if:

- you drink alcohol
- you use too much insulin
- you exercise more than usual or unexpectedly

- you eat too little or miss a meal
- you are ill.

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

- headache
- nausea
- feeling sick or very hungry
- cold sweat or cool pale skin
- short-lasting changes in your sight.
- tremor, feeling nervous, worried, fast heartbeat
- feeling unusually tired, weak and sleepy
- slurred speech, feeling confused, difficulty in concentrating.

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 some sugary food or fruit juice with you).
- Measure your blood sugar if possible and rest. 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.
- If you have type 1 diabetes and you experience multiple episodes of too low blood sugar, you should consult your doctor.

What others need to do if you pass out

Tell everyone you spend time with that you have diabetes. It is important that they recognise the signs and symptoms of a hypo.

Make sure they know to give you some sugary food or fruit juice for mild to moderate symptoms of a hypo.

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 administration 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 glucagon, you will have to be treated in a hospital.

See your doctor if you keep having hypo reactions, or if you have ever become unconscious after using insulin. Your insulin dose may need to be changed.

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.

Too high blood sugar (hyperglycaemia)

This may happen if:

- you drink alcohol
- you are ill or stressed

- you miss doses of insulin or use less insulin than you need
- you eat more carbohydrates than usual
- you exercise less than usual
- you 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:

- feeling thirsty
- flushed face or dry skin
- losing your appetite
- feeling sleepy or tired
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- dry mouth or fruity odour (acetone) on the breath
- blurred vision.

Symptoms of severe hyperglycaemia include:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness

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 unconsciousness and in extreme cases 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.

Discuss any worries you may have about this with your doctor, diabetes education nurse or pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Tresiba® affects you.

If your blood sugar is too low or too high your concentration and ability to react might be affected and therefore also your ability to drive, use any tool or operate a machine. Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car if:

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypos. If you are drinking alcohol your need for insulin may change, as your blood sugar level may either rise or fall. Careful monitoring is recommended.

Looking after your medicine

Before first use

- **Store Tresiba® Penfill® cartridges that are not being used in a refrigerator (2°C to 8°C).**
- **Do not freeze. Keep away (not too near) from the freezing element.**

After first opening or if carried as a spare

- **Do not keep the Tresiba® Penfill® that you are using in your insulin delivery device, or that you are carrying as a spare, in a refrigerator. You can use it for up to 28 days at or below 30 °C after taking it out of the refrigerator.**

Tresiba® Penfill® must not be frozen or exposed to heat or direct sunlight. Protect the medicine in Tresiba® Penfill® from light by keeping the cartridges in the carton when not in use.

Do not use Tresiba® Penfill® if the solution is not clear and colourless.

Keep it where young children cannot reach it.

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

When to discard your medicine

Discard Tresiba® Penfill® after 28 days even if there is still some medicine left in it.

Getting rid of any unwanted medicine

Dispose of used needles safely into a yellow plastic sharps container.

If your doctor tells you to stop using this medicine or the expiry date has passed, take it to any pharmacy for safe disposal.

6. Are there any side effects?

This medicine helps most people with diabetes mellitus, but it may have unwanted side effects in a few people. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, pharmacist or nurse if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <p>The most common side effect when using insulin is low blood sugar levels (a hypo).</p> <ul style="list-style-type: none">• Mild to moderate <p>Other effects:</p> | <p>Speak to your doctor, diabetes education nurse or pharmacist if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none"> ● pain, redness, hives, bruising, swelling or itching at the injection site. Usually these symptoms disappear within a few weeks during continued use. If you have serious or continuing reactions, you may need to stop using Tresiba® and use another insulin. ● a depression or thickening of the skin around the injection site (lipodystrophy). ● lumps under your skin (cutaneous amyloidosis). ● when you first start your insulin treatment you may get visual problems or swollen hands and feet. | <p>They are usually mild and short-lived.</p> |

Serious side effects

| Serious side effects | What to do |
|--|---|
| <p>Symptoms of severe low blood sugar levels:</p> <ul style="list-style-type: none"> • disorientation • seizures, fits or convulsions • loss of consciousness. <p>If a severe hypo is not treated, it can cause brain damage and death.</p> <p>Other effects:</p> <ul style="list-style-type: none"> • skin rashes over a large part of the body • shortness of breath, wheezing • swelling of the face, lips or tongue • fast pulse • sweating • signs of heart failure, such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema). | <p>Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of these serious side effects.</p> <p>You may need urgent medical attention or hospitalisation. These side effects are very rare.</p> |

Tell your doctor, diabetes education nurse or pharmacist if you notice anything else that may be making you feel unwell while you are using Tresiba®.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Tresiba® Penfill® contains

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| Active ingredient (main ingredient) | Insulin degludec Each mL of solution contains 100 units of insulin degludec. |
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| Other ingredients (inactive ingredients) | glycerol, metacresol, phenol, zinc, hydrochloric acid and sodium hydroxide (for pH adjustment) and water for injections |
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Do not take this medicine if you are allergic to any of these ingredients.

What Tresiba® Penfill® looks like

Tresiba® is a clear, colourless, aqueous solution for subcutaneous injection.

Tresiba® Penfill® is a pre-filled 3mL glass cartridge designed to be used with Novo Nordisk insulin delivery devices and NovoFine® needles.

Each pack contains 5 x 3mL cartridges (AUST R 280300)

Who distributes Tresiba® Penfill®

In Australia:

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 10

118 Mount Street,

North Sydney, NSW 2060

Australia

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For further information call the Novo Nordisk Medical Information on 1800 668 626.

www.novonordisk.com.au

You can also get more information about diabetes and insulin from Diabetes Australia

- freecall helpline 1300 136 588 (Australia)
- www.diabetesaustralia.com.au

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