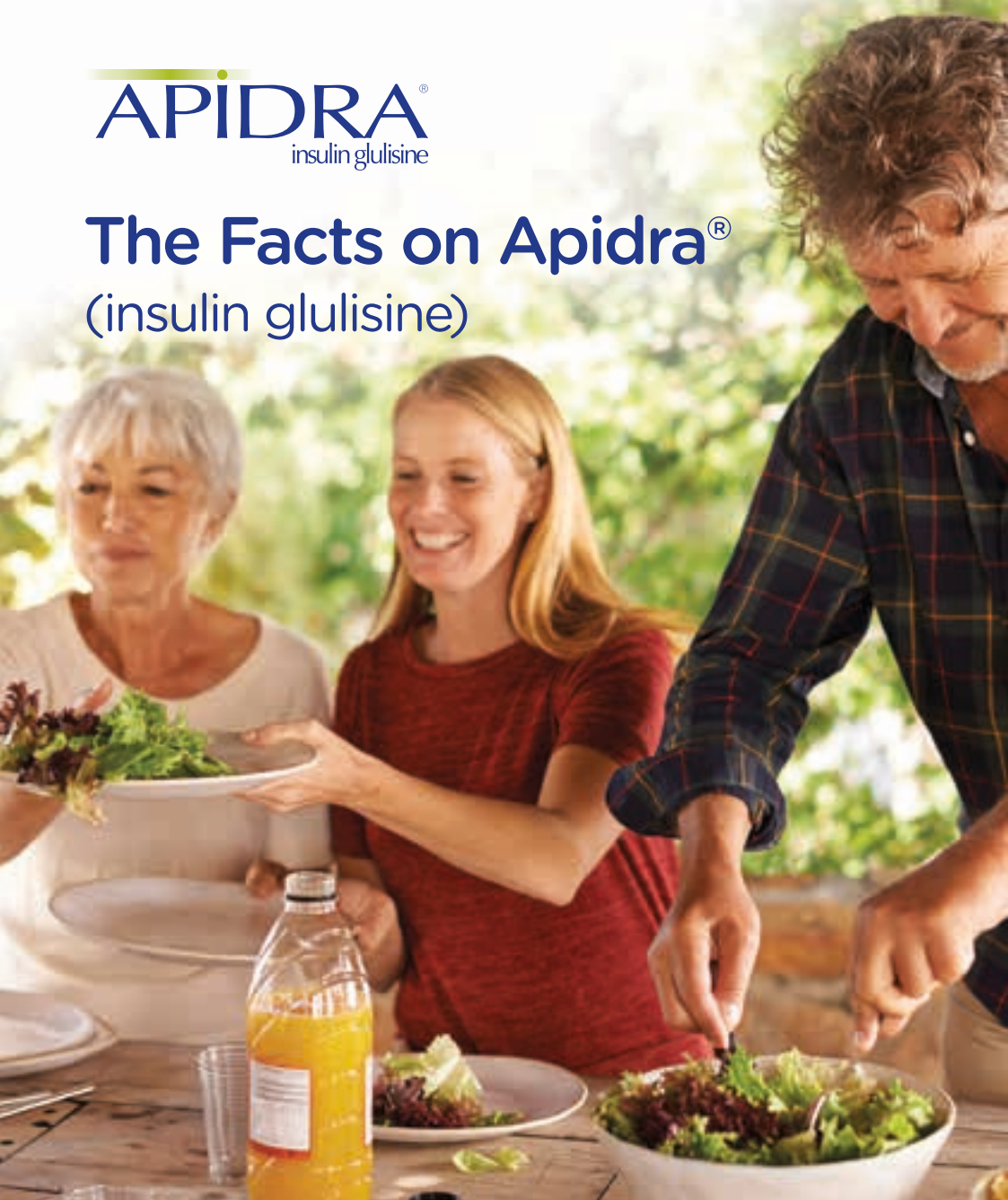


APIDRA[®]
insulin glulisine

The Facts on Apidra[®]

(insulin glulisine)



Important Contacts

General Practitioner

Name: _____

Address: _____

_____ Postcode: _____

Phone: _____

Diabetes Specialist

Name: _____

Address: _____

_____ Postcode: _____

Phone: _____

Diabetes Educator

Name: _____

Address: _____

_____ Postcode: _____

Phone: _____

Other

Important notice: The information provided in this booklet does not replace any of the information or advice provided by a medical practitioner and other members of your diabetes healthcare team. If you have any further questions about Apidra or diabetes, please contact your doctor.

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Getting started on Apidra®

You have been prescribed Apidra, which is available in¹:

A disposable pen	Or	Or
Apidra SoloSTAR® 	Apidra® 10mL vial 	Apidra® AllStar Pro® pen & Apidra® 3mL cartridges 

Apidra (insulin glulisine) is a rapid-acting meal-time (or bolus) insulin which means that it works quickly but over a short period of time to manage the rise in blood glucose that occurs after a meal. Apidra begins to work about 15 minutes after injection and continues to work for about 4 hours.¹

Apidra SoloSTAR and the cobalt blue Apidra AllStar Pro® are recommended for use with BD Micro-Fine™ Pen Needles.



- BD Micro-Fine™ 4mm
- BD Micro-Fine™ 5mm
- BD Micro-Fine™ 8mm
- BD Micro-Fine™ 12.7mm

Key information

Apidra (insulin glulisine)				
Starting dose	Breakfast ____units	Lunch ____units	Dinner ____units	Snack ____units
When	Inject Apidra within 15 minutes before or up to 20 mins from starting a meal. Your medical team will advise you on which meals to take Apidra with.			
BGL targets	My ideal BGL 2 hours after each meal is _____ This tells you whether your Apidra dose is too high or too low.			
Check my BGLs _____ times per day, ideally at _____				

Apidra dose adjustment

It may take a few adjustments to find the right dose or doses of Apidra to achieve optimal blood glucose control. By checking your blood glucose levels (BGLs) before and/or 2 hours after a meal as directed by your healthcare professional, it will help you to know whether your current dose of Apidra is right for you. It is important to stay in close contact with your healthcare professional during this time to review your BGLs and Apidra dose.

Self-managed dose adjustment option*

Increase your Apidra dose by _____ units every _____ days until your BGL measured 2 hours after the meal# is less than _____

*Stay in close contact with your healthcare professional during this adjustment period
#after the meal at which Apidra has been given

OR

Physician-led dose adjustment option

Adjust dose every _____ days.

Other instructions: _____

BGL 2 hours after the meal (mmol/L)	Change Apidra dose (units) by:

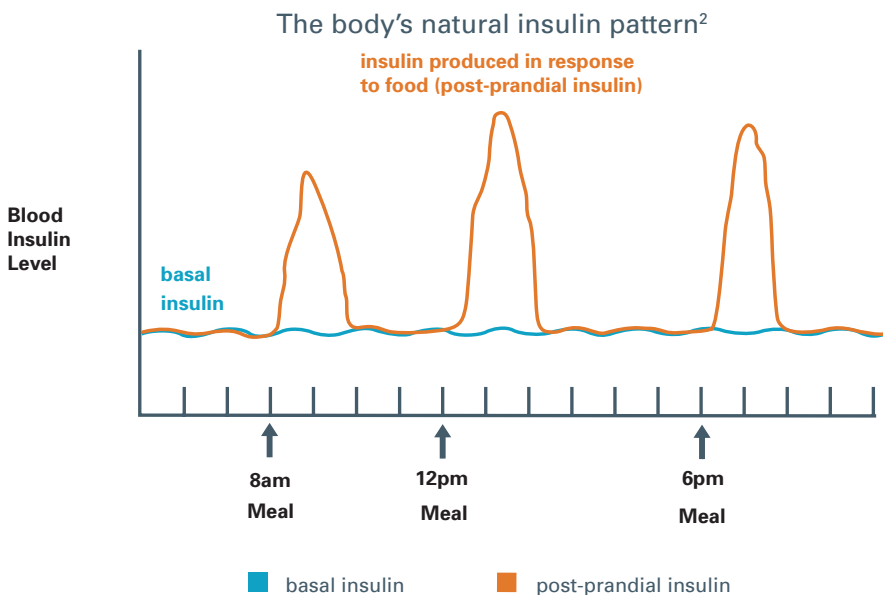
All about Apidra®

What is Apidra?

Apidra (insulin glulisine) is a rapid-acting insulin used at mealtimes to help lower blood glucose levels (BGLs) in people with Type 1 and Type 2 diabetes.

How does Apidra work?

Apidra is an analogue or modified insulin that works as a substitute for the insulin produced by the pancreas.¹ It works much like the insulin the body makes in response to food in people without diabetes. Apidra is specifically made to work rapidly at mealtimes to control the increase in BGLs that occur when you eat.



Adapted from Rosetti P *et al. Diab Care* 2008; 31(suppl 2): S113 – 120.

Is there anyone who should not take Apidra?

Do not use Apidra if you are experiencing low blood glucose levels i.e. hypoglycaemia (a 'hypo') or if you are allergic to any medicine containing insulin or any of the ingredients contained in Apidra.

Active ingredient - Insulin Glulisine (100 IU/mL).

Inactive ingredients - Meta-cresol, trometamol, sodium chloride, polysorbate 20, hydrochloric acid, sodium hydroxide, water for injections.

Before starting any insulin, tell your doctor if you are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed, or if you have had kidney or liver problems.



Using Apidra®

How is Apidra used in people with Type 1 diabetes?

In people with Type 1 diabetes, Apidra is usually used in combination with a long-acting (basal) insulin. Take care to always check which insulin you are injecting. Apidra's role is to mimic the body's normal insulin production in response to food.

How is Apidra used in people with Type 2 diabetes?

In Type 2 diabetes, Apidra can be used in conjunction with an intermediate-acting or long-acting insulin and in combination with oral diabetes medication. Apidra's role is to mimic the body's normal insulin production in response to food.

How do I use Apidra?

Apidra is available for injection in a disposable pre-filled pen called Apidra SoloSTAR®, in 3mL cartridges for use with the reusable insulin delivery pen, Apidra AllStar Pro® and 10mL vials. All forms of Apidra display a mealtime icon.

Ask your doctor or a member of your healthcare team for more information.



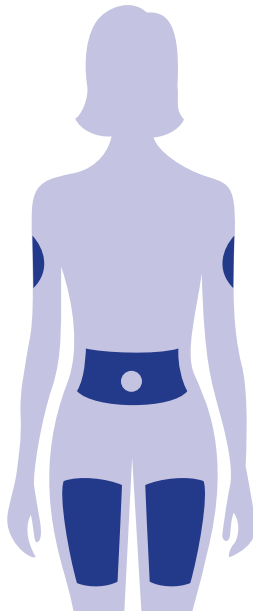
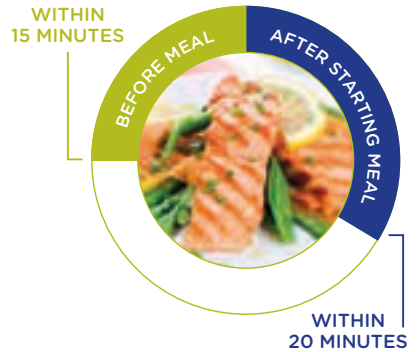
When should I take Apidra?

You can take Apidra within 15 minutes before or within 20 minutes of starting a meal. By the time your meal is digested and sugar is starting to move into the bloodstream, Apidra is 'peaking' or working its hardest to help your body move sugar from the bloodstream into cells to provide you with energy. Your doctor will advise you on how often you should take Apidra.

Where should I inject Apidra?

Your healthcare team will be able to advise you on the most appropriate injection sites for you. The abdomen (except for a five centimetre ring around the navel), the top and outer thighs and the outer, upper arms are suitable injection sites.

Regularly rotating the injection sites will reduce the chance of developing local skin reactions.¹



Recommended injection sites

Using Apidra®

What does APIDRA SoloSTAR look like?

Apidra is a clear, colourless solution. Do not use Apidra SoloSTAR if the insulin is cloudy, coloured or has particles. The pre-filled, disposable Apidra SoloSTAR pen is blue, is labelled with a meal time icon and has a dark blue injection button with a raised ring on the button. Lantus® is also available as Lantus SoloSTAR so **be careful not to confuse your insulins.**



- Apidra is a rapid-acting (meal-time) insulin and is not to be confused with Lantus, which is a long-acting (basal) insulin.
- Lantus SoloSTAR pens are grey/silver and have a flat injection button

What does Apidra AllStar Pro look like?

The Apidra AllStar Pro is to be used with the Apidra 3mL cartridges.

Apidra AllStar Pro is a cobalt blue reusable pen. In contrast, Lantus AllStar Pro is silver (gold/silver) and only Lantus cartridges should be used in this device.

Be careful not to confuse your insulins.



Mealtime icon displayed on cartridge



How should Apidra be stored?

- When in use Apidra SoloSTAR®, cartridges and vials can be stored at room temperature for 28 days (max 25°C).
- Any unopened vials, cartridges or pre-filled pens should be stored in the fridge (between +2° C and +8° C).
- Do not use Apidra if it has been frozen or exposed to excessive heat (e.g. left in the car or direct sunlight), or if it appears cloudy and has particles.
- Once in use, the open cartridges, vials and pre-filled disposable pens must be used within 28 days, after which the remaining product must be discarded.



How do I take care of my Apidra® pens?

Dirt can impede the operation of Apidra SoloSTAR® or AllStar Pro®. You can clean the outside of your Apidra pen by wiping with a damp cloth. DO NOT use cleaning agents. Do not soak, wash or lubricate the pen as this may damage it.

Should I use a new needle each time I use Apidra SoloSTAR or AllStar Pro?

Always use a new, sterile needle each time you inject. This prevents blocked needles and air bubbles. Apidra SoloSTAR® and AllStar Pro® accept needles of different lengths and gauges (thinness of needle). BD Micro-Fine™ pen needles can be used with either pen device.



Why do I need to perform a safety test each time I use Apidra SoloSTAR® or AllStar Pro®?

Each time you use these pens, you must perform a simple safety test which removes air bubbles and ensures the pen and needle are working properly.

1. Select a dose of 2 units.
2. Remove the needle caps.
3. Hold the pen with the needle pointing upwards.
4. Tap the insulin reservoir so that any air bubbles will rise up towards the needle.
5. Press the injection button all the way in and check if insulin comes out of the needle.

If no insulin comes out, the needle may be blocked. Repeat another safety test. If no insulin comes out change the needle and try again. If no insulin comes out, use another Apidra® cartridge or Apidra SoloSTAR® pen.

Are there any side effects?

The most common side effect when using any insulin is low blood glucose levels (hypoglycaemia i.e. a 'hypo'). Tell your doctor if you notice any of the following and they worry you:¹

- Hypoglycaemia (mild to moderate) see page 13 for symptoms
- Redness, swelling or itching at the injection site; usually these symptoms disappear within a few weeks during continuous use
- A depression or thickening of the skin around the injection site (caused by injecting too often at the same injection site).

If you experience any signs of an allergic reaction such as a rash, shortness of breath or swelling of the face, lips or tongue, tell your doctor immediately or go to the emergency ward at your nearest hospital.¹ These side effects are rare but potentially serious.



What if I don't feel well?

Tell your doctor if you don't feel well. Illness, especially with nausea and vomiting may cause your insulin needs to change. Work with your doctor to design a 'sick day' plan so that you know what to do, especially if you are unable to eat your normal meals.

The risk of hypoglycaemia is increased if you:³

- Accidentally use too much Apidra
- Have too much or unexpected exercise
- Delay eating meals or snacks
- Eat too little food
- Drink too much alcohol

Always carry some sugary food or drink with you.

The first symptoms of mild to moderate hypoglycaemia can come on suddenly. They may include:³

- Cold sweat, cool pale skin
- Fatigue, drowsiness, unusual tiredness and weakness
- Nervousness, anxious feeling, tremor, rapid heart beat
- Confusion, difficulty concentrating
- Excessive hunger
- Vision changes
- Headache, nausea.

If you experience any of these symptoms of hypoglycaemia, you need to raise your blood sugar urgently. You can do this by taking one of the following:^{1,3}

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- A can of a sugar-containing soft drink (not a diet soft drink)
- 2-3 concentrated glucose tablets.
- Follow up with extra carbohydrates, e.g. plain biscuits, fruit or milk, when over the initial symptoms.



Apidra® DO's and Don't's



Do's and Don'ts¹

Do

- Do inject Apidra at mealtimes as directed by your healthcare team.
- Do use a new needle for each injection.
- Do alternate injection sites.
- Do keep the Apidra SoloSTAR® or the AllStar Pro® pen with cartridges that you are using at room temperature (not greater than 25°C, and out of direct sunlight). Store unused SoloSTARs or 3mL cartridges in the fridge between 2°C and 8°C.
- Do discard any remaining Apidra 28 days after first use or removal from the fridge.

Don't

- Don't confuse your insulins
 - Apidra SoloSTAR pens are blue with a raised ring on the injection button. Lantus® SoloSTAR pens are grey/silver with a flat injection button. Always check your insulin before each injection.
- Don't mix with Lantus.
- Don't stop using Apidra without first consulting your diabetes healthcare team.
- Don't use the Apidra SoloSTAR or Apidra cartridge if it appears cloudy or if particles appear, or if you think it may have been frozen or exposed to excessive heat (above 25°C).
- If you forget to take a dose of Apidra, as with any insulin, NEVER take double to make up for a missed dose. Contact your diabetes healthcare team.

For more information about Type 1 or Type 2 diabetes or Apidra, speak with your Doctor or Diabetes Educator.

How do I know if I am taking the right dose of Apidra?

Checking your BGLs regularly before and after meals will give you the best indication of whether your Apidra dose is adequate. For example, if your BGLs 2 hours after a meal are higher than recommended by your healthcare team, your dose may not be adequate.

Your dose of Apidra may change depending on things such as weight, amount of carbohydrates eaten, level of exercise and whether you feel unwell.

Also, having an A1c (or HbA_{1c}/Haemoglobin A1c) test every three months will let you know how well you are controlling your BGLs and give you the best indication of how effective your treatment plan (e.g. medication, diet, exercise) is in controlling your BGLs. Your diabetes healthcare team will monitor your HbA_{1c} and advise you if your treatment plan is adequate.



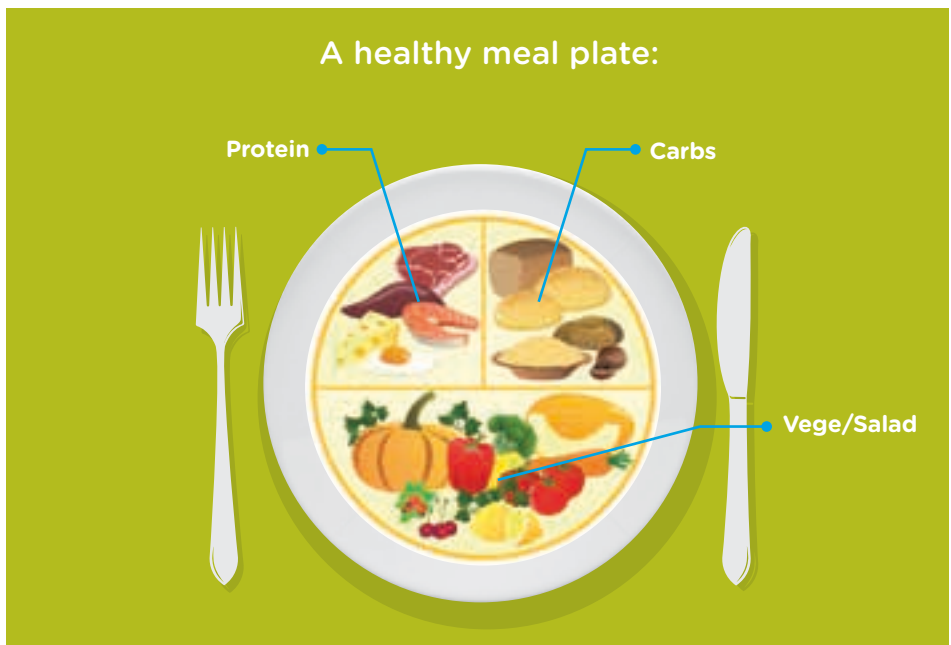
Apidra® as Part of Your Daily Routine

How do I adjust my dose of Apidra?

Your doctor and other members of your healthcare team such as a Dietitian or diabetes educator, will work with you to match your doses of Apidra with the amount and type of carbohydrates consumed. Your healthcare team may advise you to have a set number of ‘carbohydrate exchanges’ per meal and give you an appropriate Apidra dose to take. Alternatively you may be taught that you can vary the quantity of carbohydrate you eat and then match an appropriate Apidra dose – this is called “carbohydrate counting”. This process will be made easier if you keep a record of your mealtime carbohydrate, BGLs and insulin dose.

Matching your Apidra dose to the amount of carbohydrates in the foods you eat can assist in reducing the number of ‘hypos’ and help lower your A1c result.

Refer to your healthcare professionals’ instructions on page 2 of this booklet.



Will I need to adjust my dose of Apidra when exercising?

It depends on the intensity and duration of your exercise and how long after taking Apidra that the exercise occurs. Your doctor and members of your healthcare team will be able to advise on whether adjustments to your Apidra dose will be necessary.



Glossary

A1c (also called HbA_{1c} or Haemoglobin A1c): A test that shows the average amount of sugar in the blood for the past 2-3 months. This test helps your doctor or nurse to see if your blood sugar is where it needs to be.

Apidra®: Apidra (insulin glulisine) is a rapid acting insulin used at mealtimes to help lower blood glucose levels (BGLs) in people with diabetes.

Basal insulin: Works day and night to control blood sugar between meals and when you sleep (eg Lantus).

Blood glucose: The main sugar that the body makes from food. Without insulin, cells can't use blood glucose for energy. Glucose in your blood can be broken down to create energy for your body.

Blood glucose level (BGL): Is the amount of glucose in the blood.

Bolus Insulin : A bolus dose is insulin that is specifically taken at meal times to keep blood glucose levels under control following a meal. Bolus insulin needs to act quickly and so rapid acting insulin will be used (eg Apidra).

Carbohydrates: A type of food that your body needs for energy. There are two different kinds of carbohydrates, simple (meaning sugar, white bread or fruit) and complex (vegetables and starches).

Fasting blood glucose (FBG): A test to determine how much glucose (sugar) is in a blood sample after an overnight fast.

High blood glucose: When there is too much glucose in the blood. This condition can be treated with insulin.

Hyperglycaemia: The medical term for high blood sugar.

Hypoglycaemia: The medical term for low blood sugar.

Lantus®: Lantus (insulin glargine) is a long acting form of insulin used to treat type 1 and type 2 diabetes.

Low blood glucose: When there is too little glucose in the blood. This condition can happen when people with diabetes accidentally take too much insulin, exercise a lot, or don't eat enough.

Meal plan: A food guide that can help people with diabetes get the right balance of carbohydrates, proteins, and nutrients into their diet.

Pancreas: The pancreas is a gland near the stomach that makes insulin and enzymes that help digest food.

Self-monitored blood glucose (SMBG): A way for people with diabetes to check how much glucose (sugar) is in their blood. Your doctor or nurse may recommend checking your blood glucose regularly to be sure blood glucose levels are where they need to be.

Type 1 diabetes: A condition in which the pancreas can no longer produce insulin. People who have type 1 diabetes must take daily injections of long - acting and short - acting insulin.

Type 2 diabetes: A condition where the pancreas gets overworked, so it produces less insulin, or when the body becomes less sensitive to insulin that the pancreas is producing. There are several different ways to treat type 2 diabetes: diet, exercise and weight loss at first, then diabetes pills and adding insulin injections as the condition progresses.



My Action Plan



Online education about Type 2 Diabetes

Type 2 Diabetes explained

When you're diagnosed with type 2 diabetes, you need all the good information you can get. So at Sanofi, we've sponsored a free resource to give you the support tools to help manage your diabetes and live well in the real world.

ONE PERSON'S REAL STORY

The **Type 2 Diabetes Xplained** app takes a look at Type 2 diabetes in a fun, interactive way that tells the real story of a Kiwi living with diabetes – how he got there, how it has affected him and his family and how he has learnt to live with his condition.



Visit www.type2diabetesexplained.co.nz

Available in 4 languages – English, Samoan, Te Reo and Tongan.

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Useful contact details and links

Diabetes New Zealand

www.diabetes.org.nz

Diabetes Youth New Zealand

www.diabetesyouth.org.nz

For more information about Lantus or Apidra, please call 0800 LANTUS (0800 526 887 option 2).

Apidra® is a Prescription Medicine that is part of the daily treatment of Type 1 & Type 2 diabetes mellitus. Do not use if allergic to insulin glulisine or any of its ingredients.

Precautions: for subcutaneous (under the skin) injections only, only mix Apidra® with (NPH) insulin if your doctor has instructed you to do so. Close monitoring required during pregnancy, kidney or liver disease, intercurrent illness or stress. Tell your doctor if you are taking any other medicines, including those you can get from a pharmacy, supermarket or health food shop. Interactions with other medicine may increase or decrease blood glucose.

Side Effects: hyper or hypo glycaemia, injection site reactions, lipodystrophy (local disturbance of fat metabolism). Contains insulin glulisine 100u/mL. Use strictly as directed and if there is inadequate control or you have side effects see your doctor, diabetes nurse or educator.

For further information please refer to the Apidra® Consumer Medicine Information on the Medsafe website (www.medsafe.govt.nz). Sanofi New Zealand, Auckland-Freephone 0800 283 684. Apidra® is fully reimbursed when prescribed by a medical practitioner for Type 1 or Type 2 diabetes mellitus patients. Pharmacy Charges and Doctors fees apply.

Lantus® is a Prescription Medicine that is part of the daily treatment of Type 1 & Type 2 diabetes mellitus. Do not use if allergic to insulin glargine or any of its ingredients.

Precautions: for subcutaneous (under the skin) injections only, do not mix or dilute. Close monitoring required during pregnancy, kidney or liver disease, intercurrent illness or stress. Tell your doctor if you are taking any other medicines, including those you can get from a pharmacy, supermarket or health food shop. Interactions with other medicine may increase or decrease blood glucose.

Side Effects: hyper or hypo glycaemia, injection site reactions, lipodystrophy (local disturbance of fat metabolism). Contains insulin glargine 100u/mL. Use strictly as directed and if there is inadequate control or you have side effects see your doctor, diabetes nurse or educator.

For further information please refer to the Lantus® Consumer Medicine Information on the Medsafe website (www.medsafe.govt.nz). Sanofi, Auckland, freephone 0800 283 684. Lantus® is fully reimbursed when prescribed by a medical practitioner. Pharmacy charges and doctors fees apply.

References:

1. Apidra Consumer Medicine Information. July 2016.
2. Rosetti. P. et al. Diabetes Care 2008; 31 (Suppl2): S 113-120.
3. Diabetes & Insulin. Diabetes NZ. May 2015

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