

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Kirsty®

Insulin Aspart Injection

Read this carefully before you start taking **Kirsty®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Kirsty®**.

Kirsty® is a biosimilar biologic drug (biosimilar) to the reference biologic drug NovoRapid. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Contact your doctor, Diabetes Nurse Educator or pharmacist if you have any questions about this drug.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist. If you have trouble reading this, ask a family member or a friend for help.

Serious Warnings and Precautions

- Hypoglycemia is the most common adverse effect of insulin, including Kirsty®.
- If hypoglycemia or hypoglycemic reactions are not treated they can result in the loss of consciousness, coma or death.
- Glucose monitoring is recommended for all patients with diabetes.
- Any change of insulin should be made cautiously and only under medical supervision. This may result in dosage adjustment.
- Kirsty® should be given immediately before a meal because of the fast onset of action (start of the meal should be not more than 5-10 minutes after injection). (see 'How to take Kirsty®')
- Never inject your insulin directly into a vein.
- Kirsty® should not be used if it is not water-clear and colourless.

What is Kirsty® used for?

- The treatment of patients with diabetes mellitus who require insulin for the control of hyperglycemia.

How does Kirsty® work?

Kirsty® is an insulin analogue used to treat diabetes.

Kirsty® will start to lower your blood sugar 10-20 minutes after you take it, it has a maximum effect between 1 and 3 hours and the effects last for 3-5 hours. Due to this short action Kirsty® should normally be taken in combination with intermediate-acting or long-acting insulin preparations.

What are the ingredients in Kirsty®?

Medicinal ingredients: The active ingredient in Kirsty® is insulin aspart.

Non-medicinal ingredients: Disodium hydrogen phosphate dihydrate; glycerol; metacresol; phenol; sodium chloride; water for injection and zinc chloride. Hydrochloric acid and sodium hydroxide are used for pH adjustment.

Kirsty® comes in the following dosage forms:

- Kirsty® 10 mL vial
- Kirsty® 3 mL prefilled pen

Do not use Kirsty® if:

- You feel hypoglycemic reaction (low blood sugar) coming on. (see “*What are possible side effects from Kirsty®?*” for more about hypoglycemia).
- You are allergic (hypersensitive) to insulin aspart, metacresol or any of the other ingredients in this insulin. Look out for the signs of an allergic reaction. (see “*What are possible side effects from Kirsty®?*”)
- The protective cap is loose or missing. Each vial has a protective, tamper proof plastic cap. If the cap is not in perfect condition when you get the vial, return the vial to your supplier.
- The insulin has not been stored correctly or if it has been frozen. (see “*How to store Kirsty®*”)
- The insulin does not appear water-clear and colourless.

As a precautionary measure, you should carry a spare syringe and extra insulin in case the insulin delivery device is lost or damaged.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Kirsty®. Talk about any health conditions or problems you may have, including if you:

- Have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands, your doctor may decide to alter your insulin dose.
- Drink alcohol (including wine and beer) your need for insulin may change as your blood sugar level may either rise or fall.
- Have an infection, fever or have had an operation you may need more insulin than usual.
- Suffer from diarrhea, vomiting or eat less than usual you may need less insulin than usual.
- Exercise more than usual or if you want to change your usual diet.
- Are ill: continue taking your insulin. Your need for insulin may change.
- Go abroad: travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travel.
- Are pregnant, or planning a pregnancy or are breastfeeding please contact your doctor for advice.
- Drive or use tools or machines: watch for signs of a hypoglycemia. Your ability to concentrate or to react will be less during a hypoglycemic reaction. Please keep this in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). Never drive or use machinery if you feel a hypoglycemic reaction coming on.

Discuss with your doctor whether you should drive or use machines at all, if you have a lot of hypoglycemic reactions or if you find it hard to recognize hypoglycemia.

Before you travel, check with your doctor or pharmacist on the availability of Kirsty® in other countries. If possible, bring enough Kirsty® with you on your trip.

Thiazolidinediones (class of oral antidiabetic drugs) used together with insulin may increase risk of oedema and heart failure. Inform your doctor as soon as possible if you experience localised

swelling (oedema) or signs of heart failure such as unusual shortness of breath.

Hypokalemia (low potassium) is a possible side effect with all insulins. You might be more at risk if you are on potassium lowering drugs or losing potassium (e.g. diarrhea).

Insulin aspart has a rapid onset of effect therefore if hypoglycemia occurs, you may experience it earlier after an injection when compared to soluble human insulin.

Other warnings you should know about:

- You may have a very rare serious allergic reaction to Kirsty or one of its ingredients (called a generalized allergic reaction). See also the warning in “Do not use Kirsty if”.
- **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, pitted, or thickened area. Tell your healthcare professional if you notice any skin changes at the injection site. Tell your healthcare professional if you are currently injecting into these affected areas before you start injecting in a different area. A sudden change of site may result in hypoglycemia. Your healthcare professional may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Kirsty®:

Some medicines affect the way glucose works in your body and this may influence your insulin dose. Listed below are the most common medicines, which may affect your insulin treatment. Tell your doctor, Diabetes Nurse Educator or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, you should tell your doctor if you are using any medicine as mentioned below that affects your blood sugar level.

If you take any of the medicines below, your blood sugar level may fall (hypoglycemia)

- Other medicines for the treatment of diabetes
- Monoamine oxidase inhibitors (MAOI) (used to treat depression)
- Beta-blockers (used to treat high blood pressure)
- Angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure)
- Salicylates (used to relieve pain and lower fever)
- Anabolic steroids (such as testosterone)
- Sulfonamides (used to treat infections)

If you take any of the medicines below, your blood sugar level may rise (hyperglycemia)

- Oral contraceptives (birth control pills)
- Thiazides (used to treat high blood pressure or excessive fluid retention)
- Glucocorticoids (such as ‘cortisone’ used to treat inflammation)
- Thyroid hormones (used to treat thyroid gland disorders)
- Sympathomimetics (such as epinephrine [adrenaline], or salbutamol, terbutaline used to treat asthma)

- Growth hormone (medicine for stimulation of skeletal and somatic growth and pronounced influence on the body's metabolic processes)
- Danazol (medicine acting on ovulation)

Octreotide and lanreotide (used for treatment of acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults, caused by the pituitary gland producing excess growth hormone) may either increase or decrease your blood sugar level.

Beta-blockers (used to treat high blood pressure) may weaken or suppress entirely the first warning symptoms which help you to recognise a hypoglycemia.

How to take Kirsty®:

Kirsty® is for injection under the skin (subcutaneously).

Kirsty® 10 mL vial is also for continuous infusion in a pump system. Kirsty® may also be given intravenously by healthcare professionals under close supervision by a doctor.

Always vary the site you inject within the same region, to avoid lumps (see 'What are possible side effects from using Kirsty®?'). The best places to give yourself an injection are: the front of your thighs, the front of your waist (abdomen), the upper arm, or the buttocks. Your insulin will work more quickly if you inject into the front of your waist.

You should always measure your blood glucose regularly.

Talk about your insulin needs with your doctor and Diabetes Nurse Educator. Do not change your insulin unless your doctor tells you to. Follow their advice carefully. This leaflet is a general guide only. If your doctor has switched you from one type or brand of insulin to another, your dose may have to be adjusted by your doctor.

Due to the faster onset of action, Kirsty® should be given close to a meal (start of the meal should be no more than 5-10 minutes after the injection). When necessary, Kirsty® can be given soon after a meal, instead of before the meal.

Before using Kirsty®

- Check the label to make sure you have the right type of insulin.
- Remove the protective cap.
- Always use a new needle for each injection to prevent contamination.
- Needles and syringes must not be shared. Do not reuse or share needles with another person including family members. You may give another person an infection or get an infection from them.
- Kirsty® pre-filled pen is only suitable for injecting under the skin. Speak to your doctor if you need to inject your insulin by another method.

Always use your insulin and adjust your dose exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

If you use only one type of insulin [vial]

- Draw into the syringe the same amount of air as the dose of insulin you are going to inject. Inject the air into the vial.
- Turn the vial and syringe upside down and draw the correct insulin dose into the syringe.

Pull the needle out of the vial. Then expel the air from the syringe and check that the dose is correct.

How to inject this insulin [vial]

- Pinch your skin between two fingers, push the needle into the skin fold and inject the insulin under the skin.
- Keep the needle under your skin for at least 6 seconds to make sure you have injected all the insulin.
- Discard the needle after each injection.

For use in an infusion pump system [vial]:

Kirsty® should never be mixed with any other insulin when used in a pump.

Follow the instructions and recommendations from your doctor regarding the use of Kirsty® in a pump. Before using Kirsty® in a pump system you must receive comprehensive instructions in its use and information about any actions to be taken in case of illness; too high or too low blood sugar; or failure of the pump system.

- Before inserting the needle, use soap and water to wash your hands and the skin around the area where the needle is inserted so as to avoid any infection at the infusion site.
- When you fill a new reservoir, be certain not to leave large air bubbles in either the syringe or the tubing.
- Changing the infusion set (tubing and needle) must be done according to the instructions in the product information supplied with the infusion set.

To get the benefit of insulin infusion, and to detect a possible malfunction of the insulin pump, you should measure your blood sugar level regularly.

What to do in case of pump system failure

You should always have alternative insulin available for injection under the skin in case of pump system failure.

How to inject this insulin [pre-filled pen]

- Kirsty® is for injection under the skin (subcutaneously). You must never inject yourself directly into vein (intravenously) or muscle (intramuscularly). Use the injection technique advised by your healthcare professional.
- Keep the needle under your skin for at least six seconds. Keep the push button fully depressed until the needle has been withdrawn. This will ensure correct delivery and limit possible flow of blood into the needle or insulin reservoir.
- After each injection be sure to discard the needle. Otherwise, the liquid may leak out when the temperature changes.

Overdose:

If you think you have taken too much Kirsty®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Causes of a hypoglycemia:

You get a hypoglycemia if your blood sugar gets too low.

This might happen:

- If you take too much insulin.

- If you eat too little or miss a meal.
- If you exercise more than usual.

The warning signs of a hypoglycemia may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heartbeat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; and difficulty concentrating.

If you get any of these signs: eat glucose tablets or a high sugar snack (sweets, biscuits, fruit juice), then rest. Don't take any insulin if you feel a hypoglycemia coming on. Carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

Tell your relatives, friends and close colleagues that if you pass out (become unconscious), they must turn you on your side and get medical help right away. They must not give you anything to eat or drink as it could choke you.

- If severe hypoglycemia is not treated, it can cause brain damage (temporary or permanent) and even death.
- If you have a hypoglycemia that makes you pass out, or if you get a lot of hypoglycemias, talk to your doctor. The amount or timing of your insulin dose, the amount of food you eat or the amount of exercise you do, may need to be adjusted.

Using glucagon

You may recover more quickly from unconsciousness with an injection of the hormone glucagon given by someone who knows how to use it. If you are given glucagon, you will need to eat glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Contact your doctor or hospital emergency after an injection of glucagon: you need to find the reason for your hypoglycemia in order to avoid getting more.

Causes of a hyperglycemia:

You get a hyperglycemia if your blood sugar gets too high.

This might happen:

- If you forget to take insulin.
- If you repeatedly take less insulin than you need.
- If you eat more than usual.
- If you exercise less than usual.

The warning signs appear gradually. They include: increased urination; feeling thirsty; losing your appetite; feeling sick (nausea or vomiting); feeling drowsy or tired; flushed dry skin; a dry mouth and a fruity (acetone) smelling breath.

These may be signs of a very serious condition called diabetic ketoacidosis. If you don't treat it, this could lead to diabetic coma and death.

If you get any of these signs: test your blood sugar level; test your urine for ketones if you can; then seek medical advice right away.

What are possible side effects from using Kirsty®?

These are not all the possible side effects you may feel when taking Kirsty®. If you experience any side effects not listed here, contact your healthcare professional.

Like all medicines, Kirsty® can cause side effects, although not everybody gets them. The most common side effect is low blood sugar (hypoglycemia). See the advice in ‘How to take Kirsty®?’.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
LESS COMMON (1 to 10 users in 1000)			
Signs of allergy: Hives and rash may occur.		√	√
Vision problems: disruption of vision when treatment is first started (temporary).	√		
Changes at the injection site (lipodystrophy): Lipoatrophy or lipohypertrophy.		√	
Swollen joints: When you start taking in insulin, water retention may cause swelling around your ankles and other joints. This soon disappears	√		
Diabetic retinopathy (eye background changes): If you have diabetic retinopathy and your blood glucose levels improve very fast, the retinopathy may get worse.		√	
RARE (less than 1 user in 10,000)			
Painful neuropathy (nerve related pain): If your blood glucose levels improve very fast you may get nerve related pain. This is called acute painful neuropathy and is usually transient.	√		
UNKNOWN			
Cutaneous Amyloidosis: Lumps under skin.		√	

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of the reach and sight of children. Keep Kirsty® protected from heat or light.

Do not use Kirsty® after the expiry date printed on the label and carton.

10 mL vial:

Before opening: Store in a refrigerator at 2°C to 8°C, away from the cooling element. Do not freeze. Protect from light.

During use or when carried as a spare: Store below 30°C. The product may be stored for a maximum of 4 weeks. Do not refrigerate or freeze

Kirsty® should not be disposed of in waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

Pre-filled pen:

Before opening: Kirsty® pre-filled pen that is not being used is to be stored in the refrigerator at 2°C to 8°C, away from the cooling element. Do not freeze.

During use or when carried as a spare: You can carry your Kirsty® pre-filled pen with you and keep it at a temperature below 30°C or in a refrigerator (2°C to 8°C) for up to 4 weeks. If refrigerated, keep away from the cooling element. Do not freeze.

The Kirsty® pre-filled pen you are using should be thrown away after 4 weeks, even if it still has insulin left in it. Do not use this medication after the expiration date stated on the label.

What Kirsty® looks like and package content

Kirsty® comes as a water-clear, colourless, aqueous solution in packages of one 10 mL vial per carton.

Kirsty® pre-filled pen comes as a water-clear, colourless, aqueous solution in packages of 1 or 5 prefilled pens of 3 mL per carton.

1 mL contains 100 U (units) of insulin aspart.
1 vial contains 10 mL of insulin aspart equivalent to 1000 U.
1 prefilled pen contains 3 mL insulin aspart equivalent to 300 U.

If you want more information about Kirsty®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); by calling 1-833-986-1468 or medical.informationCanada@biocon.com

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Instructions for Use:

Kirsty® pre-filled pen

Read the following instructions carefully before using your Kirsty® pre-filled pen. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too high or too low blood sugar level.

Do not use the pen without proper training from your doctor or nurse. If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use the pre-filled pen.

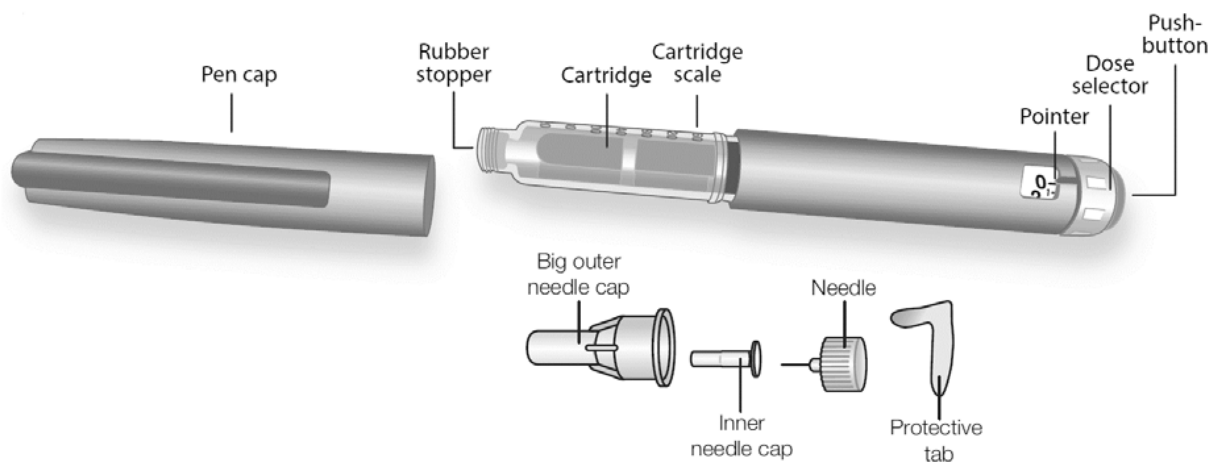
Kirsty® pre-filled Pen is a prefilled dial-a-dose insulin pen. You can select doses from 1 to 80 units in increments of 1 unit.

Needle sizes compatible with this pen:

- 31G, 5 mm
- 32G, 4 mm
- 34G, 4mm

As a precautionary measure, always carry a spare insulin delivery device in case you Kirsty® pre-filled pen is lost or damaged.

Kirsty® pre-filled pen



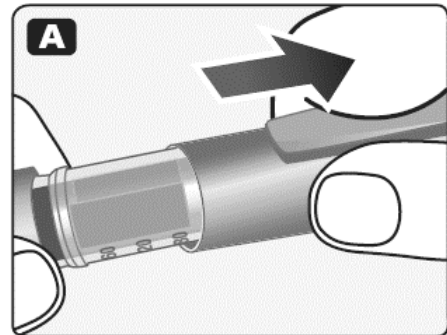
Preparing your Kirsty® pre-filled pen

Wash your hands before using the pen.

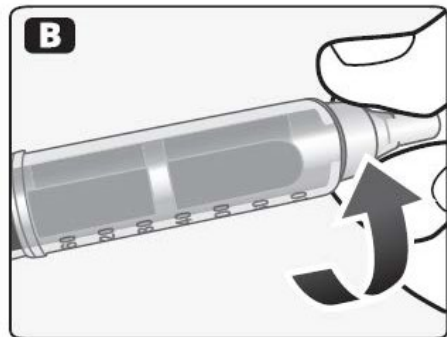
Check the name (Kirsty) on the label of your blue pen with orange button to make sure that it contains the correct type of insulin. This is especially important if you take more than one type of insulin. If you take the wrong type of insulin, your blood sugar level may get too high or too low.

Check the insulin in the cartridge. Kirsty® should be clear, colourless and free of particles. If not, do not use.

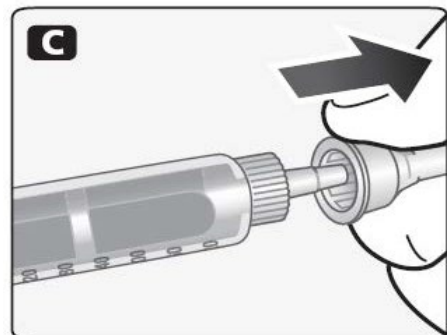
A. Pull off the pen cap.
Wipe the rubber stopper with an alcohol swab.



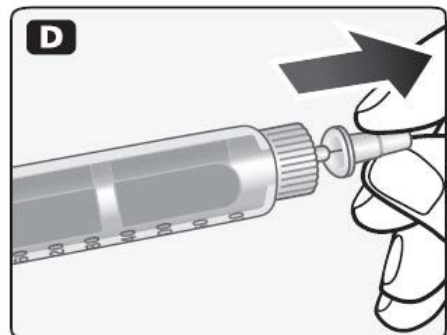
B. Remove the paper tab from a new disposable needle.
Screw the needle straight and tightly onto your Kirsty® pre-filled pen.



C. Pull off the big outer needle cap and keep it for later.



D. Pull off the inner needle cap and dispose of it.
Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.



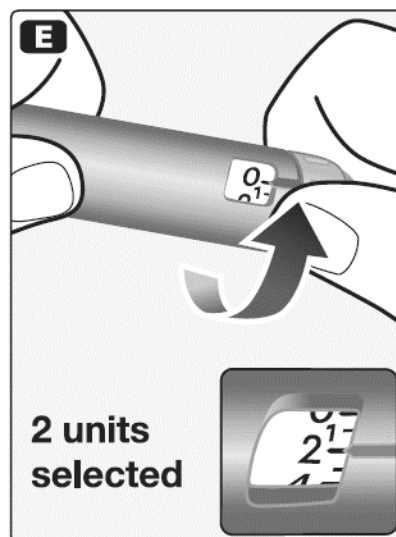
⚠ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

⚠ Be careful not to bend or damage the needle before use.

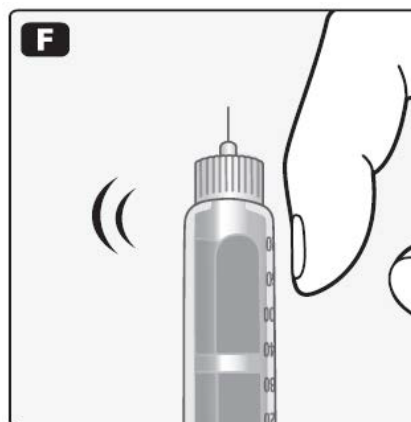
Checking the insulin flow

Prior to each injection small amounts of air may collect in the cartridge during normal use. To avoid injection of air and ensure proper dosing:

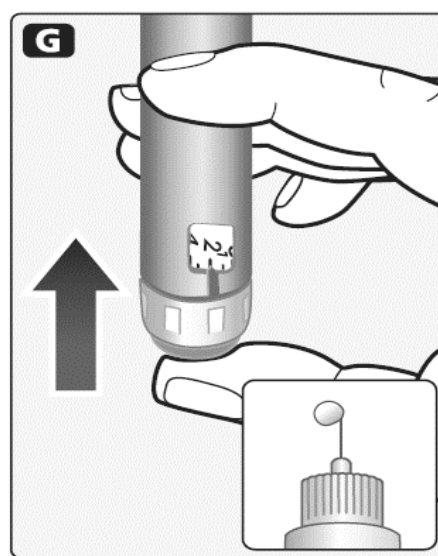
- E.** Turn the dose selector to select 2 units.





- F.** Hold your Kirsty® pre-filled pen with the needle pointing upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge.



- G.** Keeping the needle upwards, press the push-button all the way in. The dose selector returns to 0. A drop of insulin should appear at the needle tip. If not, change the needle and repeat the procedure no more than 6 times. If a drop of insulin still does not appear, the pen is defective, and you must use a new one.



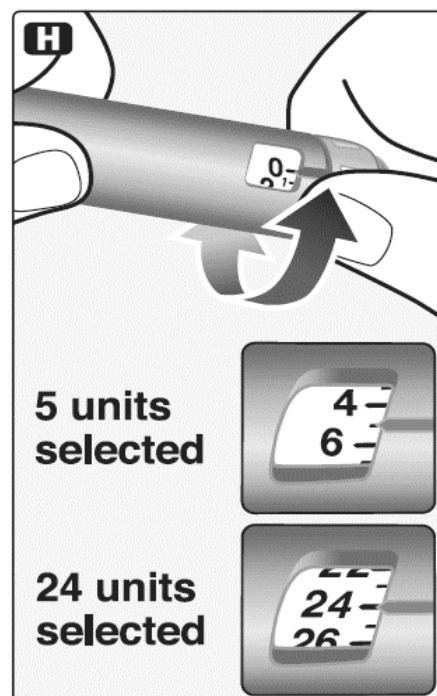
 Always make sure that a drop appears at the needle tip before you inject. This makes sure that the insulin flows. If no drop appears, you will not inject any insulin, even though the dose selector may move. This may indicate a blocked or damage needle.


 Always checks the flow before you inject. If you do not check the flow, you may get too little insulin or no insulin at all. This may lead to too high blood sugar level.


Selecting your dose

Check that the dose selector is set at 0.

H. Turn the dose selector to the number of units you need to inject.
The dose can be corrected either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer. When turning the dose selector, be careful not to push the push-button as insulin will come out.
You cannot select a dose larger than the number of units left in the cartridge.



 Always use the dose selector and the pointer to see how many units you have selected before injecting the insulin.

 Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the residual scale, it only shows approximately how much insulin is left in your pen.

Giving the injection

Use the injection technique shown by your doctor or nurse.

Kirsty® can be injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs (thighs) or upper arms.

For each injection change (rotate) your injection site within the area of skin that you use. **Do not** use the same injection site for each injection.

I. Insert the needle into your skin. Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.

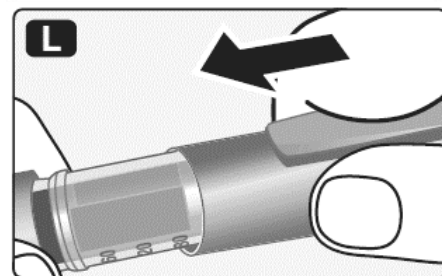
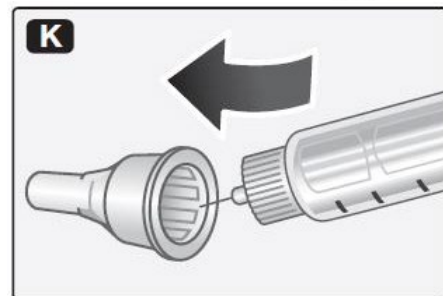
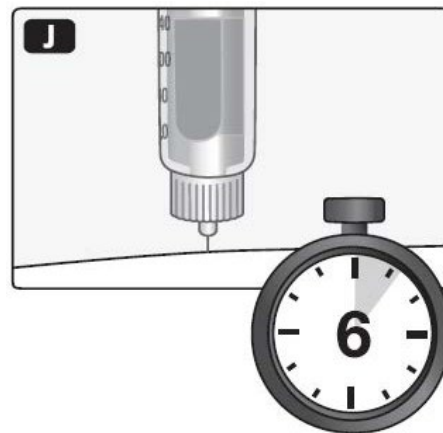
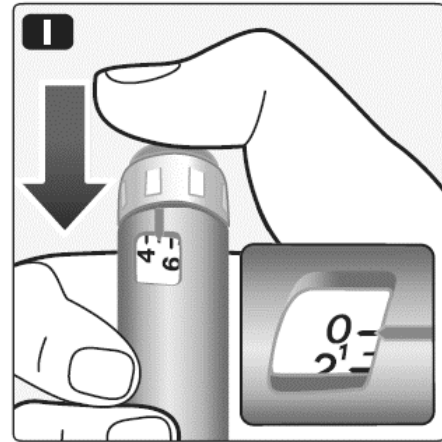
Turning the dose selector will not inject insulin.

J. Keep the push-button fully depressed and let the needle remain under the skin for at least 6 seconds. This will make sure you get the full dose. Withdraw the needle from the skin, then release the pressure on the push-button.

Always make sure that the dose selector returns to 0 after the injection. If the dose selector stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar level.

K. Lay the outer needle cap on a flat surface and carefully insert the needle into the cap. Do not touch the needle. Once the needle is covered push the cap on and unscrew the needle. Safely remove the needle from your Kirsty® pre-filled pen after each use.
Dispose of needle in a suitable sharp's container.

L. Put the pen cap on the Kirsty® pre-filled pen and store the pen without the needle attached.



Caring for your pen

Your Kirsty® pre-filled pen must be handled with care. If it is dropped, damaged, or crushed, there is a risk of insulin leakage. This may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

You can clean the exterior of your Kirsty® pre-filled pen by wiping it with a medicinal swab. Do not soak it, wash or lubricate it as it may damage the pen.

Do not refill your Kirsty® pre-filled pen. Once empty, it must be disposed of.

Important information

- Always keep your pen with you.
- Always carry an extra pen and new needles with you. In case of loss or damage.
- Always keep your pen and needles out of sight and reach of others, especially children.
- Never share your pen or your needles with other people. It might lead to cross-infection.
- Never share your pen with other people. Your medicine might be harmful to their health.
- Caregivers must be very careful when handling used needles to reduce the risk of needle injury and cross-infection.

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