Kirsty™

Insulin Aspart Injection (rDNA Origin) 100 U/mL

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1) What Kirsty™ is used for

Kirsty™ is used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of your blood sugar.

2) How Kirsty™ works

Kirsty™ is a modern insulin (insulin analogue) with a rapid-acting effect. Modern insulin products are improved versions of human insulin.

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

3) Before you use Kirsty™

When you must not use it

- **If you are allergic** to insulin aspart, or any of the other ingredients in this medicine.
- **If you suspect hypoglycaemia** (low blood sugar) is starting
- **If the protective cap** is loose or missing. Each vial/cartridge has a protective, tamper-proof plastic cap. If it is not in perfect condition when you get the vial/cartridge, return the vial/cartridge to your supplier.
- **If it has not been stored correctly** or been frozen
- **If the insulin does not appear clear and colourless.**

Before you start to use it

- **Check the label to make sure** it is 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.
- **Skin changes at the injection site**: The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area. Contact your doctor if you are currently injecting into a lumpy area 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.

Taking other medicines

Some medicines affect the way glucose works in your body and this may influence your insulin dose. The most common medicines which may affect your insulin treatment are listed below. Tell your doctor, nurse or pharmacist if you take or have recently taken any other medicines, including medicines obtained without a prescription. In particular, you should tell your doctor if you use any medicine listed below that may affect your blood sugar level.

If you take any of the following medicines, your blood sugar level may fall (hypoglycaemia):

Oral antidiabetic medicinal products, monoamine oxidase inhibitors (MAOI), beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.

If you take any of the following medicines, your blood sugar level may rise (hyperglycaemia):

Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.

Octreotide and lanreotide may either increase or decrease your blood sugar level.

Beta-blockers may weaken or suppress entirely the first warning symptoms which help you to recognise a hypoglycaemia.

Thiazolidinediones (class of oral antidiabetic medicines used for treatment of type 2 diabetes mellitus)

Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who are treated with thiazolidinediones in combination with insulin may develop heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

4) How to use Kirsty™

How much to use

Talk about your insulin dose with your doctor and nurse. Make sure you use your colour-coded Kirsty™ as your doctor and nurse have told you and follow their advice carefully.

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. Do not change your insulin unless your doctor tells you to.

Use in Children

Kirsty™ can be used in adolescents and children aged 1 year and above instead of soluble human insulin when a rapid onset of effect is preferred. For example, when it is difficult to dose the child in relation to meals.

Use in special patient groups

If you have reduced kidney or liver function, or if you are above 65 years of age, you need to check your blood sugar more regularly and discuss changes in your insulin dose with your doctor

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When to use it

Kirsty™ is generally taken immediately before a meal. Eat a meal or snack within 10 minutes of the injection to avoid low blood sugar. When necessary, Kirsty™ can be given soon after a meal.

How to use it

Kirsty™ **is for injection under the skin** (subcutaneously) or for continuous infusion in a pump system. Administration in a pump system will require a comprehensive instruction by your healthcare professional. Kirsty™ may also be given directly into a vein (intravenously) by physicians or other healthcare staff if applicable. Never inject your insulin directly into a muscle (intramuscularly).

Always vary the sites you inject within the same region to reduce the risk of developing lumps or skin pitting. The best places to give yourself an injection are: the front of your waist (abdomen); the upper arm or the front of your thighs. The insulin will work more quickly if you inject into the waist (abdomen). You should measure your blood sugar regularly.

How to use cartridge

The Kirsty™ ® cartridges are to be used only in conjunction with a compatible insulin injector pen. The manufacturer's instructions for using the pen must be followed carefully for loading the cartridge, attaching the needle, and administering the insulin injection. Keep the cartridge at room temperature for 1 or 2 hours before inserting it in the pen. Look at the cartridge before you use it. Only use it if the solution is clear, colourless and has no visible particles in it. Do not shake or mix it before use. Always use a new cartridge if you notice that your blood sugar control is unexpectedly getting worse. This is because the insulin may have lost some of its effectiveness. If you think you may have a problem with Kirsty™ have it checked by your doctor or pharmacist. Do not re-fill and re-use empty cartridges. Do not add any other insulin to the cartridge. Do not mix Kirsty™ with any other insulins or medicines. Do not dilute it. Mixing or diluting may change the action of Kirsty™.

How to use Vial

Look at the vial before you use it. Only use it if the solution is clear, colourless and has no visible particles in it. Do not shake or mix it before use. Make sure that neither alcohol nor other disinfectants or other substances contaminate the insulin. Do not mix Kirsty™ with any other insulins or medicines. Do not dilute it. Mixing or diluting may change the action of Kirsty™ Always use a new vial if you notice that your blood sugar control is unexpectedly getting worse. This is because the insulin may have lost some of its effectiveness. If you think you may have a problem with Kirsty™ have it checked by your doctor or pharmacist. Inject the insulin under the skin. Use the injection technique advised by your doctor or diabetes nurse. Keep the needle under your skin for at least 6 seconds to make sure that the full dose has been delivered.

Inject the insulin:

- Inject the insulin under the skin. Use the injection technique advised by your doctor or diabetes nurse.
- Keep the needle under your skin for at least 6 seconds to make sure that the full dose has been delivered.

How long to use it

Continue taking Kirsty™ for as long as your doctor recommends. Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycemia and diabetic ketoacidosis.

If you forget to use it

If you forget to take your insulin your blood sugar may get too high (hyperglycaemia).
This may also happen:
• If you repeatedly take less insulin than you need.
• If you get an infection or a fever.
• 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; dry mouth and a fruity (acetone) smell of the breath. These may be signs of a very serious condition called diabetic ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar). If you do not treat it, this could lead to diabetic coma and eventually death. If you get any of the signs mentioned above, test your blood sugar level, test your urine for ketones if you can, then seek medical advice immediately.

If you have injected too much Kirsty™

If you take too much insulin your blood sugar gets too low (hypoglycaemia).
Hypoglycaemia may also happen:
• If you eat too little or miss a meal.
• If you exercise more than usual.

The warning signs of a hypoglycaemia 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; difficulty in concentrating.

If you feel a hypoglycaemic episode coming on, take a high sugar snack and then measure your blood sugar.

If your blood sugar is too low, eat glucose tablets or another high sugar snack (sweets, biscuits, fruit juice), then rest.

When the symptoms of hypoglycaemia have disappeared or when your blood sugar level is stabilised, continue insulin treatment.

You may recover more quickly from unconsciousness with an injection of the hormone glucagon by someone who knows how to use it. If you are given glucagon, you

will need 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 an emergency ward after an injection of glucagon; you need to find the reason for your hypoglycaemia to avoid getting more.

Kirsty™ has a rapid effect. Therefore, if hypoglycaemia occurs, you may experience it earlier after an injection when compared to soluble human insulin.

If you stop using
Do not stop taking your insulin without speaking with a doctor, who will tell you what needs to be done. This could lead to very high blood sugar (severe hyperglycaemia) and ketoacidosis. See c) Effects from diabetes in section 6.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

5) While you are using Kirsty™
Things you must do
Eat a meal or snack containing carbohydrates within 10 minutes of the injection to avoid hypoglycaemia.

Things you must not do
Do not take any insulin if you feel a hypo coming on.

Always carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

Tell relevant people you have diabetes and what the consequences may be, including the risk of passing out (becoming unconscious) due to a hypo.

Tell relevant people that if you pass out, they must turn you on your side and get medical help straight away. They must not give you any food or drink. It could choke you.

- If prolonged severe hypoglycaemia is not treated, it can cause brain damage (temporary or permanent) and even death.
- If you have a hypo that makes you pass out, or a lot of hypos, talk to your doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

Things you must be careful of
Some conditions and activities can affect your need for insulin. Consult your doctor:
- **If you have trouble** with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.
- **If you exercise** more than usual or if you want to change your usual diet, as this may affect your blood sugar label
- **If you are ill**, carry on taking your insulin and consult your doctor.
- **If you are going abroad:** travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travelling.
- **If you drink alcohol,** your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

Driving and using machines

Please ask your doctor whether you can drive a car or operate a machine:
- If you have frequent hypoglycaemia.
- If you find it hard to recognise hypoglycaemia.

If your blood sugar is low or high, your concentration and ability to react might be affected and therefore also your ability to drive or operate a machine. Bear in mind that you could endanger yourself or others.

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

Kirsty™ contains sodium

Kirsty™ contains less than 1 mmol sodium (23 mg) per dose, i.e. Kirsty™ is essentially 'sodium-free'

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant, planning a pregnancy or breast-feeding, please contact your doctor for advice. Kirsty™ can be used during pregnancy and breast-feeding. Your insulin dosage may need to be changed during pregnancy and after delivery. Careful control of your diabetes, particularly prevention of hypoglycaemia, is important for the health of your baby.

6) Side effects
Like all medicines, Kirsty™ can cause side effects, although not everybody gets them. Side effects may occur with certain frequencies, which are defined as follows:
- Very common: affects more than 1 user in 10
- Uncommon: affects 1 to 10 users in 1,000
- Rare: affects 1 to 10 users in 10,000
- Very rare: affects less than 1 user in 10,000

Very common side effects
Low blood sugar (hypoglycaemia).
Uncommon side effects
Vision problems. When you first start your insulin treatment, it may disturb your vision, but the disturbance is usually temporary.

Changes at the injection site (**lipodystrophy and cutaneous amyloidosis**). The fatty tissue under the skin at the injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). Changing the site with each injection reduces the risk of developing such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or nurse. These reactions can become more severe, or they may change the absorption of your insulin if you inject in such a site.

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Signs of allergy. Reactions (pain, redness, hives, inflammation, swelling and itching) at the injection site may occur (local allergic reactions). These usually disappear after a few weeks of taking your insulin. If they do not disappear, see your doctor.

Seek medical advice immediately:
►If signs of allergy spread to other parts of your body, or
►If you suddenly feel unwell, and you start sweating; start being sick (vomiting); have difficulty in breathing; have a rapid heartbeat; feel dizzy.

Diabetic retinopathy (an eye disease related to diabetes which can lead to loss of vision). If you have diabetic retinopathy and your blood sugar level improves very fast, the retinopathy may get worse. Ask your doctor about this.

Swollen joints. When you start taking insulin, water retention may cause swelling around your ankles and other joints. Normally this soon disappears.

Rare side effects
Painful neuropathy (pain due to nerve damage). If your blood sugar level improves very fast, you may get nerve related pain, this is called acute painful neuropathy and is usually transient.

Very rare side effects
Serious allergic reaction to Kirsty™ or one of its ingredients (called a systemic allergic reaction).
If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03- 78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7) Storage and Disposal of Kirsty™

Storage:

Keep out of the reach and sight of children. Do not use Kirsty™ after the expiry date which is stated on the carton and on the label of the vial/cartridge after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator at temperature between 2°C to 8°C. Do not freeze. Do not exposed to excessive heat or direct sunlight.

<u>During use or when carried as a spare vials/cartridges:</u>

The solution can be kept at room temperature not above 30°C for up to 28 days once the vial/cartridge has been put to use. Do not refrigerate. Do not freeze.

Do not expose to excessive heat or direct sunlight. Do not use it after this time period. It is recommended that the date of the first use be noted on the label. Do not use Kirsty™ if you notice particles in it. Only use Kirsty™ if the solution is clear and colourless. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Disposal:

Any unused product or waste material should be disposed of in accordance with local requirements. Kirsty™ formulations should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

8) Product Description

<u>*What us looks like*</u>
The solution is clear and colourless

Presentation
i) 10 mL Vial
ii) 3 mL Cartridge

<u>*Ingredients*</u>

Active Ingredients
Insulin Aspart 100 U/mL

Inactive Ingredients
Glycerol, Phenol, Metacresol, Zinc chloride, Disodium phosphate dihydrate, Sodium chloride, Hydrochloric acid, Sodium hydroxide and Water for injections

<u>*MAL Number*</u>
MAL21016004AZ

9) Manufacturer, Product Registration Holder and Released by:
Biocon Sdn. Bhd.
No.1, Jalan Bioteknologi 1,
Kawasan Perindustrian SiLC,
79200 Iskandar Puteri, Johor, Malaysia.

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Lot No. 2, 4, 6, 8, & 10, Jalan P/7, Section 13, Bangi Industrial Estate,
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Selangor Darul Ehsan, Malaysia.

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17/03/2023

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