*For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory*

Biocon Biologics™

# Kirsty®

## Insulin Aspart for Injection (r-DNA origin)

**Solution for Subcutaneous Injection in Pre-filled Pen**

**100 U/ mL**

**1 pre-filled pen with 3 mL of solution**

**COMPOSITION**

1 ml solution contains 100 units (equivalent to 3.5 mg) insulin aspart*.

Kirsty 100 units/ml solution for injection in pre filled pen

Each pre filled pen contains 3 ml equivalent to 300 units.

*Insulin aspart is produced in Pichia pastoris by recombinant DNA technology.

For the full list of excipients, see **"List of Excipients"** section.

**PHARMACEUTICAL FORM**

Solution for injection (injection).

The solution is clear, colourless and aqueous.

**PHARMACOLOGICAL PROPERTIES**

**Pharmacodynamic properties**

**Pharmacotherapeutic group** - Drugs used in diabetes. Insulins and analogues for injection, fast acting. ATC code: A10AB05.

Kirsty is a biosimilar medicinal product.

**Mechanism of action and pharmacodynamic effects**

The blood glucose lowering effect of insulin aspart is due to the facilitated uptake of glucose following binding of insulin to receptors on muscle and fat cells and to the simultaneous inhibition of glucose output from the liver.

Insulin aspart produces a more rapid onset of action compared to soluble human insulin, together with a lower glucose concentration, as assessed within the first four hours after a meal. Insulin aspart has a shorter duration of action compared to soluble human insulin after subcutaneous injection.

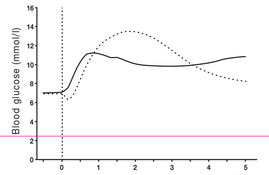


Fig. 1. Blood glucose concentrations following a single pre meal dose of insulin aspart injected immediately before a meal (solid curve) or soluble human insulin administered 30 minutes before a meal (hatched curve) in patients with type 1 diabetes mellitus.

When insulin aspart is injected subcutaneously, the onset of action will occur within 10 to 20 minutes of injection. The maximum effect is exerted between 1 and 3 hours after injection. The duration of action is 3 to 5 hours.

**Clinical efficacy and safety**

Clinical trials in patients with type 1 diabetes have demonstrated a lower postprandial blood glucose with insulin aspart compared to soluble human insulin (Fig. I). In two long term open label trials in patients with type 1 diabetes comprising 1070 and 884 patients, respectively, insulin aspart reduced glycated haemoglobin by 0.12 [95% C.I. 0.03; 0.22] percentage points and by 0.15 [95% C.I. 0.05; 0.26] percentage points compared to human insulin; a difference of limited clinical significance.

Clinical trials in patients with type 1 diabetes have demonstrated a reduced risk of nocturnal hypoglycaemia with insulin aspart compared with soluble human insulin. The risk of daytime hypoglycaemia was not significantly increased.

Insulin aspart is equipotent to soluble human insulin on a molar basis.

**Special populations**

*Elderly (≥ 65 years old)*

A randomised, double blind cross over PK/PD trial comparing insulin aspart with soluble human insulin was performed in elderly patients with type 2 diabetes (19 patients aged 65 83 years, mean age 70 years). The relative differences in the pharmacodynamic properties (GIRmax, AUCGIR, 0 120 min) between insulin aspart and soluble human insulin in the elderly were similar to those seen in healthy subjects and in younger patients with diabetes.

*Paediatric population*

A clinical trial comparing preprandial soluble human insulin with postprandial insulin aspart was performed in small children (20 patients aged 2 to less than 6 years, studied for 12 weeks, among those four were younger than 4 years old) and a single dose PK/PD trial was performed in children (6 12 years) and adolescents (13 17 years). The pharmacodynamic profile of insulin aspart in children was similar to that seen in adults.

The efficacy and safety of insulin aspart given as bolus insulin in combination with either insulin detemir or insulin degludec as basal insulin has been studied for up to 12 months, in two randomised controlled clinical trials in adolescents and children aged 1 to less than 18 years (n=712). The trials included 167 children aged 1 5 years, 260 aged 6 11 and 285 aged 12 17. The observed improvements in HbA1c and the safety profiles were comparable between all age groups.

*Pregnancy*

A clinical trial comparing safety and efficacy of insulin aspart vs. human insulin in the treatment of pregnant women with type 1 diabetes (322 exposed pregnancies (insulin aspart: 157; human insulin: 165)) did not indicate any adverse effect of insulin aspart on pregnancy or on the health of the foetus/newborn.

In addition, the data from a clinical trial including 27 women with gestational diabetes randomised to treatment with insulin aspart vs. human insulin (insulin aspart: 14; human insulin: 13) showed similar safety profiles between treatments.

**Pharmacokinetic properties**

Absorption, distribution and elimination

In Kirsty substitution of amino acid proline with aspartic acid at position B28 reduces the tendency to form hexamers as observed with soluble human insulin. Kirsty is therefore more rapidly absorbed from the subcutaneous layer compared to soluble human insulin.

The time to maximum concentration is, on average, half of that for soluble human insulin. A mean maximum plasma concentration of 492±256 pmol/l was reached 40 (interquartile range: 30 40) minutes after a subcutaneous dose of 0.15 unit/kg bodyweight in type 1 diabetic patients. The insulin concentrations returned to baseline about 4 to 6 hours after dose. The absorption rate was somewhat slower in type 2 diabetic patients, resulting in a lower Cmax (352±240 pmol/l) and later tmax (60 (interquartile range: 50 90) minutes). The intra individual variability in time to maximum concentration is significantly less for Kirsty than for soluble human insulin, whereas the intra individual variability in Cmax for Kirsty is larger.

**Special populations**

*Elderly (≥ 65 years old)*

The relative differences in pharmacokinetic properties between insulin aspart and soluble human insulin in elderly patients (65 83 years, mean age 70 years) with type 2 diabetes were similar to those observed in healthy subjects and in younger patients with diabetes. A decreased absorption rate was observed in elderly patients, resulting in a later tmax (82 (interquartile range: 60 120) minutes), whereas Cmax was similar to that observed in younger patients with type 2 diabetes and slightly lower than in patients with type 1 diabetes.

*Hepatic impairment*

A single dose pharmacokinetic study of insulin aspart was performed in 24 subjects with hepatic function ranging from normal to severely impaired. In patients with hepatic impairment, absorption rate was decreased and more variable, resulting in delayed tmax from about 50 min in subjects with normal hepatic function to about 85 min in patients with moderate and severe hepatic impairment. AUC, Cmax and CL/F were similar in patients with reduced hepatic function compared with subjects with normal hepatic function.

*Renal impairment*

A single dose pharmacokinetic study of insulin aspart in 18 subjects with renal function ranging from normal to severely impaired was performed. No apparent effect of creatinine clearance values on AUC, Cmax, CL/F and tmax of insulin aspart was found. Data were limited in patients with moderate and severe renal impairment. Patients with renal failure necessitating dialysis treatment were not investigated.

*Paediatric population*

The pharmacokinetic and pharmacodynamic properties of insulin aspart were investigated in children (6 12 years) and adolescents (13 17 years) with type 1 diabetes. Insulin aspart was rapidly absorbed in both age groups, with similar tmax as in adults. However, Cmax differed between the age groups, stressing the importance of the individual titration of insulin aspart.

**Preclinical safety data**

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development.

In in vitro tests, including binding to insulin and IGF 1 receptor sites and effects on cell growth, insulin aspart behaved in a manner that closely resembled human insulin. Studies also demonstrate that the dissociation of binding to the insulin receptor of insulin aspart is equivalent to human insulin.

**CLINICAL PARTICULARS**

**Therapeutic indications**

Kirsty is indicated for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.

**Posology and method of administration**

**Posology**

The potency of insulin analogues, including insulin aspart, is expressed in units, whereas the potency of human insulin is expressed in international units.

Kirsty dosing is individual and determined in accordance with the needs of the patient. It should normally be used in combination with intermediate acting or long acting insulin.

Moreover, Kirsty vial can be used for continuous subcutaneous insulin infusion (CSII) in pump systems.

Kirsty vial can also be used if intravenous administration of insulin aspart, by physicians or other healthcare staff, is applicable.

Blood glucose monitoring and insulin dose adjustments are recommended to achieve optimal glycaemic control.

The individual insulin requirement in adults and children is usually between 0.5 and 1.0 unit/kg/day. In a basal bolus treatment regimen 50 70% of this requirement may be provided by Kirsty and the remainder by intermediate acting or long acting insulin.

Adjustment of dose may be necessary if patients undertake increased physical activity, change their usual diet or during concomitant illness.

**Special populations**

*Elderly (≥ 65 years old)*

Kirsty can be used in elderly patients.

In elderly patients, glucose monitoring should be intensified, and the insulin aspart dose adjusted on an individual basis.

*Renal impairment*

Renal impairment may reduce the patient's insulin requirements.

In patients with renal impairment, glucose monitoring should be intensified, and the insulin aspart dose adjusted on an individual basis.

*Hepatic impairment*

Hepatic impairment may reduce the patient's insulin requirements.

In patients with hepatic impairment, glucose monitoring should be intensified, and the insulin aspart dose adjusted on an individual basis.

*Paediatric population*

Kirsty can be used in children and adolescents aged 1 year and above in preference to soluble human insulin when a rapid onset of action might be beneficial, for example, in the timing of the injections in relation to meals (see **Pharmacodynamic Properties** and **Pharmacokinetics Properties** section).

The safety and efficacy of Kirsty in children below 1 year of age have not been established.

No data are available.

*Transfer from other insulin medicinal products*

When transferring from other insulin medicinal products, adjustment of the Kirsty dose and the dose of the basal insulin may be necessary. Kirsty has a faster onset and a shorter duration of action than soluble human insulin. When injected subcutaneously into the abdominal wall, the onset of action will occur within 10 20 minutes of injection. The maximum effect is exerted between 1 and 3 hours after the injection. The duration of action is 3 to 5 hours.

Close glucose monitoring is recommended during the transfer and in the initial weeks thereafter (see **Special warnings and precautions for use** section).

**Method of administration**

Insulin aspart is a rapid acting insulin analogue.

Kirsty is administered subcutaneously by injection in the abdominal wall, the thigh, the upper arm, the deltoid region or the gluteal region. Injection sites should always be rotated within the same region in order to reduce the risk of lipodystrophy and cutaneous amyloidosis (see **Special warnings and precautions for use and Undesirable effects** sections). Subcutaneous injection in the abdominal wall ensures a faster absorption than other injection sites. Compared to soluble human insulin the faster onset of action of Kirsty is maintained regardless of the injection site. The duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity.

Due to the faster onset of action, Kirsty should generally be given immediately before a meal. When necessary Kirsty can be given soon after a meal.

*Kirsty 100 units/ml solution for injection in pre filled pen*

Kirsty pre filled pen is only suitable for subcutaneous injections. If administration by syringe or intravenous injection is necessary, a vial should be used. If administration by infusion pump is necessary, a vial should be used.

Kirsty pre filled pen delivers insulin in increment of 1 unit up to a maximum single dose of 80 units. Kirsty pre filled pen is designed to be used with commercially available insulin pen needles. See also **Special precautions for disposal and other handling** section.

For detailed user instructions, please refer to the package leaflet.

**Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in List of excipients section.

**Special warnings and precautions for use**

*Traceability*

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered medicinal product should be clearly recorded.

*Travel*

Before travelling between different time zones, the patient should seek the doctor's advice since this may mean that the patient has to use the insulin and meals at different times.

*Hyperglycaemia*

Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia and diabetic ketoacidosis. Usually the first symptoms of hyperglycaemia develop gradually over a period of hours or days. They include thirst, increased frequency of urination, nausea, vomiting, drowsiness, flushed dry skin, dry mouth, loss of appetite as well as acetone odour of breath. In type 1 diabetes, untreated hyperglycaemic events eventually lead to diabetic ketoacidosis, which is potentially lethal.

*Hypoglycaemia*

Omission of a meal or unplanned, strenuous physical exercise may lead to hypoglycaemia.

Especially in children, care should be taken to match insulin doses (especially in basal bolus regimens) with food intake, physical activities and current blood glucose level in order to minimise the risk of hypoglycaemia.

Hypoglycaemia may occur if the insulin dose is too high in relation to the insulin requirement. In case of hypoglycaemia or if hypoglycaemia is suspected Kirsty must not be injected. After stabilization of patient's blood glucose adjustment of the dose should be considered (see **Undesirable effects** and **Overdose** sections).

Patients whose blood glucose control is greatly improved, e.g. by intensified insulin therapy, may experience a change in their usual warning symptoms of hypoglycaemia, and should be advised accordingly. Usual warning symptoms may disappear in patients with longstanding diabetes.

A consequence of the pharmacodynamics of rapid acting insulin analogues is that if hypoglycaemia occurs, it may occur earlier after an injection when compared with soluble human insulin.

Since Kirsty should be administered in immediate relation to a meal, the rapid onset of action should be considered in patients with concomitant diseases or treatment where a delayed absorption of food might be expected.

Concomitant illness, especially infections and feverish conditions, usually increases the patient's insulin requirements. Concomitant diseases in the kidney, liver or affecting the adrenal, pituitary or thyroid gland can require changes in the insulin dose.

When patients are transferred between different types of insulin medicinal products, the early warning symptoms of hypoglycaemia may change or become less pronounced than those experienced with their previous insulin.

*Transfer from other insulin medicinal products*

Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand (manufacturer), type, origin (animal, human insulin or human insulin analogue) and/or method of manufacture (recombinant DNA versus animal source insulin) may result in the need for a change in dose. Patients transferred to Kirsty from another type of insulin may require an increased number of daily injections or a change in dose from that used with their usual insulin medicinal products. If an adjustment is needed, it may occur with the first dose or during the first few weeks or months.

*Injection site reactions*

As with any insulin therapy, injection site reactions may occur and include pain, redness, hives, inflammation, bruising, swelling and itching. Continuous rotation of the injection site within a given area reduces the risk of developing these reactions. Reactions usually resolve in a few days to a few weeks. On rare occasions, injection site reactions may require discontinuation of Kirsty.

*Skin and subcutaneous tissue disorders*

Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site from an affected to an unaffected area, and dose adjustment of antidiabetic medications may be considered.

*Combination of insulin aspart with pioglitazone*

Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. This should be kept in mind if treatment with the combination of pioglitazone and insulin aspart is considered. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs.

*Avoidance of accidental mix ups/medication errors*

Patients must be instructed to always check the insulin label before each injection to avoid accidental mix ups between insulin aspart and other insulin products.

*Insulin antibodies*

Insulin administration may cause insulin antibodies to form. In rare cases, the presence of such insulin antibodies may necessitate adjustment of the insulin dose in order to correct a tendency to hyper or hypoglycaemia.

*Sodium*

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

**Interaction with other medicinal products and other forms of interaction**

A number of medicinal products are known to interact with the glucose metabolism.

The following substances may reduce the patient's insulin requirements: Oral antidiabetic medicinal products, monoamine oxidase inhibitors (MAOI), beta blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulphonamides.

The following substances may increase the patient's insulin requirements: Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.

Beta blockers may mask the symptoms of hypoglycaemia.

Octreotide/lanreotide may either increase or decrease the insulin requirement.

Alcohol may intensify or reduce the hypoglycaemic effect of insulin.

**Fertility, pregnancy, and lactation**

*Pregnancy*

Kirsty can be used in pregnancy. Data from two randomized controlled clinical trials (322 and 27 exposed pregnancies) do not indicate any adverse effect of insulin aspart on pregnancy or on the health of the foetus/newborn when compared to human insulin (see **Pharmacodynamic properties** section).

Intensified blood glucose control and monitoring of pregnant women with diabetes (type 1 diabetes, type 2 diabetes or gestational diabetes) are recommended throughout pregnancy and when contemplating pregnancy. Insulin requirements usually fall in the first trimester and increase subsequently during the second and third trimester. After delivery, insulin requirements normally return rapidly to pre pregnancy values.

*Breast feeding*

There are no restrictions on treatment with Kirsty during breast feeding. Insulin treatment of the nursing mother presents no risk to the baby. However, the Kirsty dose may need to be adjusted.

*Fertility*

Animal reproduction studies have not revealed any differences between insulin aspart and human insulin regarding fertility.

**Effects on ability to drive and use machines**

The patient's ability to concentrate and react may be impaired as a result of hypoglycaemia. This may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery).

Patients should be advised to take precautions to avoid hypoglycaemia while driving. This is particularly important in those who have reduced or absent awareness of the warning signs of hypoglycaemia or have frequent episodes of hypoglycaemia. The advisability of driving should be considered in these circumstances.

**Undesirable effects**

*Summary of the safety profile*

Adverse reactions observed in patients using insulin aspart are mainly due to the pharmacologic effect of insulin.

The most frequently reported adverse reaction during treatment is hypoglycaemia. The frequencies of hypoglycaemia vary with patient population, dose regimens and level of glycaemic control (see **Undesirable effects** section, Description of selected adverse reactions).

At the beginning of the insulin treatment, refraction anomalies, oedema and injection site reactions (pain, redness, hives, inflammation, bruising, swelling and itching at the injection site) may occur. These reactions are usually of transitory nature. Fast improvement in blood glucose control may be associated with acute painful neuropathy, which is usually reversible. Intensification of insulin therapy with abrupt improvement in glycaemic control may be associated with temporary worsening of diabetic retinopathy, while long term improved glycaemic control decreases the risk of progression of diabetic retinopathy.

*Tabulated list of adverse reactions*

Adverse reactions listed below are based on clinical trial data and classified according to MedDRA frequency and System Organ Class. Frequency categories are defined according to the following convention: Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000); not known (cannot be estimated from the available data).

| MedDRA system organ class | Very Common | Uncommon | Rare | Very Rare | Not Known |
|---|---|---|---|---|---|
| Immune system disorders | | Urticaria, rash, eruptions | | Anaphylactic reactions* | |
| Metabolism and nutrition's disorders | Hypoglycaemia* | | | | |
| Nervous system disorders | | | Peripheral neuropathy (painful neuropathy) | | |
| Eye disorders | | Refraction disorders, diabetic retinopathy | | | |
| Skin and subcutaneous tissue disorders | | Lipodystrophy* | | | Cutaneous amyloidosis*† |
| General disorders and administration site conditions | | Injection site reactions, oedema | | | |

*see **Undesirable effects** section, Description of selected adverse reactions.

† adverse drug reaction (ADR) from postmarketing sources.

*Description of selected adverse reactions*

*Anaphylactic reactions*

The occurrence of generalized hypersensitivity reactions (including generalized skin rash, itching, sweating, gastrointestinal upset, angioneurotic oedema, difficulties in breathing, palpitation and reduction in blood pressure) is very rare but can potentially be life threatening.

Hypoglycaemia

The most frequently reported adverse reaction is hypoglycaemia. It may occur if the insulin dose is too high in relation to the insulin requirement. Severe hypoglycaemia may lead to unconsciousness and/or convulsions and may result in temporary or permanent impairment of brain function or even death. The symptoms of hypoglycaemia usually occur suddenly. They may include cold sweats, cool pale skin, fatigue, nervousness or tremor, anxiousness, unusual tiredness or weakness, confusion, difficulty in concentration, drowsiness, excessive hunger, vision changes, headache, nausea and palpitation.

In clinical trials, the frequency of hypoglycaemia varied with patient population, dose regimens and level of glycaemic control. During clinical trials the overall rates of hypoglycaemia did not differ between patients treated with insulin aspart compared to human insulin.

*Skin and subcutaneous tissue disorders*

Lipodystrophy (including lipohypertrophy, lipoatrophy) and cutaneous amyloidosis may occur at the injection site and delay local insulin absorption. Continuous rotation of the injection site within the given injection area may help to reduce or prevent these reactions (see **Special warnings and precautions for use** section).

*Paediatric population*

Based on post marketing sources and clinical trials, the frequency, type and severity of adverse reactions observed in the paediatric population do not indicate any differences to the broader experience in the general population.

*Other special populations*

Based on post marketing sources and clinical trials, the frequency, type and severity of adverse reactions observed in the elderly patients and in patients with renal or hepatic impairment do not indicate any differences to the broader experience in the general population.

*Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

**Overdose**

A specific overdose for insulin cannot be defined, however, hypoglycaemia may develop over sequential stages if too high doses relative to the patient's requirement are administered:

- Mild hypoglycaemic episodes can be treated by oral administration of glucose or sugary products. It is therefore recommended that the diabetic patient always carries sugar containing products.
- Severe hypoglycaemic episodes, where the patient has become unconscious, can be treated with glucagon (0.5 to 1 mg) given intramuscularly or subcutaneously by a trained person, or with glucose given intravenously by physicians or other healthcare staff. Glucose must be given intravenously, if the patient does not respond to glucagon within 10 to 15 minutes. Upon regaining consciousness, administration of oral carbohydrates is recommended for the patient in order to prevent a relapse.

**PHARMACEUTICAL PARTICULARS**

**List of excipients**

Glycerol
Phenol
Metacresol
Zinc chloride
Disodium phosphate dihydrate
Sodium chloride
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injections

**Incompatibilities**

This medicinal product must not be diluted or mixed with other medicinal products.

**Shelf life**

*Before opening*

30 months

*After first opening*

28 days

Chemical and physical in use stability has been demonstrated for 31 days at 30°C and 5°C. From a microbiological point of view, once opened, the medicinal product may be stored for a maximum of 28 days at 30°C.

Other in use storage times are the responsibility of the user.

*Kirsty 100 units/ml solution for injection in prefilled pen*

Store below 30°C. Can be stored in a refrigerator (2°C¬ 8°C). Do not freeze.

Keep the pen cap on the pen in order to protect from light.

**Special precautions for storage**

Store in a refrigerator (2°C 8°C). Do not freeze.

Keep the medicinal product in the outer carton in order to protect from light.

For storage conditions of the medicinal product after first opening, see **Shelf life** section.

**Nature and contents of container**

*Kirsty 100 units/ml solution for injection in prefilled pen*

3 ml solution in cartridge (type 1 glass) with a plunger and stopper (bromobutyl) and aluminium seal contained in a multidose pre-filled pen.

Pack sizes of 1, 5, 10 pre-filled pens, or a multipack containing 10 (2 packs of 5) pre-filled pens.

**Special precautions for disposal and other handling**

Do not use this medicinal product if you notice that the solution is not clear, colourless and aqueous.

Kirsty which has been frozen must not be used.

The patient should be advised to discard the needle after each injection.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Needles, syringes, and pre-filled pens must not be shared.

Kirsty 100 units/ml solution for injection in pre-filled pen

The needle sizes compatible with this pen are:

- 31G, 5 mm,
- 32G, 4 6 mm,
- 34G, 4 mm.

**Name and address of the manufacturer(s) of the biological active substance(s)**

Biocon Sdn. Bhd.,
No. 1, Jalan Bioteknologi 1,
Kawasan Perindusterian SiLC, 79200 Iskandar Puteri,
Johor, Malaysia

**Name and address of the manufacturer responsible for batch release**

Kirsty pre-filled pen:

McDermott Laboratories T/A Mylan Dublin Biologics Newenham Court
Northern Cross Malahide Road Dublin, 17, Ireland.

**Product owner:**
**Biocon SDN BHD ;**
No. 1, Jalan Bioteknologi 1, Kawasan perindustrian SiLC,
Johor, 79200, Iskandar Puteri (Formerly Nusajaya), Malaysia

*For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory*

Biocon Biologics™

Kirsty®

Insulin Aspart for Injection (r-DNA origin)

**Solution for Subcutaneous Injection in Pre-filled Pen**

**100 U/ mL**

**1 pre-filled pen with 3 mL of solution**

BM/XXXX/XX

**For further details, please contact:**

**Medical Advisor / Medical Affairs**
**Biocon Biologics Ltd**
Biocon House - Semicon Park
Electronic city Phase II
Bangalore – 560100

**Note: Unless otherwise stated and claimed, the data related to the studies, tests, treatment and application contained herein are from the published databases.**

**Kirsty® is registered by Biocon Biologics Limited.**

To report adverse events and/or product complaints visit our website www.biocon.com or e-mail us at DrugSafety@biocon

Leaflet generated August 2023

Biocon Biologics™

440 mm

750 mm

Size: 750 (W) x 440 (H) mm ; Colour : ■ PANTONE Black C
Folding Size: 43.33mm-9 folds, 30mm-1 fold, 20mm-1 fold x 150 (H) mm with pasting
Note : **Booklet to be sealed with 2 stickers** ; Paper: **60 gsm Maplitho / SMPO Paper**
**Folding & Pharmacode position to be followed as per Drawing No. 70M1806504**

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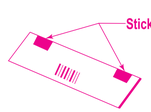
Note : Booklet to be sealed with
2 numbers of transparent perforated stickers.

Size:13x30mm plain perforated tape WITH MATT VARNISH
Material : UPM 6L/RP37/01 PP CLEAR TC50/RP37/WG65




**PHARMA CODE:**