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Kirsty[1] (*insulin aspart*)

An overview of Kirsty and why it is authorised in the EU

What is Kirsty and what is it used for?

Kirsty is a medicine used to control blood glucose (sugar) levels in patients from one year of age who have diabetes.

Kirsty is a 'biosimilar medicine'. This means that Kirsty is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Kirsty is NovoRapid. For more information on biosimilar medicines, see here.

Kirsty contains the active substance insulin aspart.

How is Kirsty used?

Kirsty can only be obtained with a prescription. It is given as an injection under the skin in the upper arm, thigh, buttock or belly. Because Kirsty is a fast-acting insulin, it is usually given shortly before a meal or if more appropriate, soon after a meal. Kirsty is normally used in combination with a longer-acting insulin. The dose is worked out for each patient and depends on the patient's weight and blood glucose levels.

Kirsty can also be used in a pump system for continuous insulin infusion under the skin or alternatively, it can be given into a vein but only by a doctor or a nurse.

A healthcare professional should explain to the patient how to use the medicine properly.

For more information about using Kirsty, see the package leaflet or contact your doctor or pharmacist.

How does Kirsty work?

In diabetes, patients have high levels of blood glucose either because the body does not produce enough insulin or the body is unable to use insulin effectively.

The active substance in Kirsty is a form of insulin which is absorbed more quickly by the body than regular insulin, and can therefore act faster. It helps control blood glucose levels, thereby alleviating symptoms of diabetes and reducing the risk of complications.

[1] Previously known as Kixelle.

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What benefits of Kirsty have been shown in studies?

Laboratory studies comparing Kirsty with NovoRapid have shown that the active substance in Kirsty is highly similar to that in NovoRapid in terms of structure, purity and biological activity. Studies have also shown that giving Kirsty produces similar levels of the active substance in the body to giving NovoRapid.

In addition, Kirsty was shown to be comparable with another licensed insulin aspart medicine in maintaining a stable HbA1c (a measure of blood glucose control) when used as part of diabetes treatment in a study involving 478 patients with diabetes. Average HbA1c was 7.85% at the start of treatment, and 7.93% after 24 weeks among those given Kirsty; this compared with values of 7.80% at start of treatment and 7.82% after 24 weeks in those given the licensed insulin aspart.

Because Kirsty is a biosimilar medicine, the studies on effectiveness and safety of insulin aspart carried out with NovoRapid do not all need to be repeated for Kirsty.

What are the risks associated with Kirsty?

The safety of Kirsty has been evaluated, and on the basis of all the studies carried out the side effects of the medicine are considered to be comparable to those of the reference medicine NovoRapid.

The most common side effect with Kirsty (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose levels) and the medicine must not be given to people whose blood glucose level is already low.

For the full list of side effects and restrictions with Kirsty, see the package leaflet.

Why is Kirsty authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Kirsty has a highly similar structure, purity and biological activity to NovoRapid and is distributed in the body in the same way. In addition, studies in patients with diabetes have shown that the safety and effectiveness of Kirsty is equivalent to that of NovoRapid.

All these data were considered sufficient to conclude that Kirsty will behave in the same way as NovoRapid in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for NovoRapid, the benefits of Kirsty outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Kirsty?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Kirsty have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Kirsty are continuously monitored. Side effects reported with Kirsty are carefully evaluated and any necessary action taken to protect patients.

Other information about Kirsty

Kixelle received a marketing authorisation valid throughout the EU on 5 February 2021.

The name of the medicine was changed to Kirsty on 16 July 2021.

Further information on Kirsty can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/kirsty.

This overview was last updated in 08-2021.