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Truvelog Mix 30 (*insulin aspart*)

An overview of Truvelog Mix 30 and why it is authorised in the EU

What is Truvelog Mix 30 and what is it used for?

Truvelog Mix 30 is an insulin medicine used to treat patients from 10 years of age who have diabetes and need insulin to keep their blood glucose (sugar) level controlled.

Truvelog Mix 30 is a 'biosimilar medicine'. This means that Truvelog Mix 30 is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Truvelog Mix 30 is NovoMix 30. For more information on biosimilar medicines, see here.

Truvelog Mix 30 contains the active substance insulin aspart combined with protamine to make it longer acting.

How is Truvelog Mix 30 used?

Truvelog Mix 30 can only be obtained with a prescription and is given as an injection under the skin in the upper arm, thigh, buttock or belly, usually shortly before a meal or, if more appropriate, soon after a meal. The dose is worked out for each patient and depends on the patient's weight and blood glucose level.

In type 2 diabetes, Truvelog Mix 30 can be given on its own or together with other diabetes medicines.

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

For more information about using Truvelog Mix 30, see the package leaflet or contact your doctor or pharmacist.

How does Truvelog Mix 30 work?

In diabetes, patients have high levels of blood glucose because either the body does not produce enough insulin or the body is unable to use insulin effectively. Truvelog Mix 30 is a replacement insulin that helps control blood glucose levels, thereby alleviating symptoms of diabetes and reducing the risk of complications.

The insulin aspart in Truvelog Mix 30 is a form of insulin which is absorbed more quickly by the body than regular insulin and can therefore start working sooner after it is injected. In Truvelog Mix 30, 30%

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

of the active substance is in this rapid acting form, and 70% in a longer acting form combined with protamine (insulin aspart protamine), which is absorbed more slowly and so works for longer.

What benefits of Truvelog Mix 30 have been shown in studies?

Laboratory studies comparing Truvelog Mix 30 with NovoMix 30 have shown that the active substance in Truvelog Mix 30 is highly similar to that in NovoMix 30 in terms of structure, purity and biological activity. Studies have also shown that giving Truvelog Mix 30 produces similar levels of the active substance in the body to giving NovoMix 30.

Because Truvelog Mix 30 is a biosimilar medicine, the studies on effectiveness and safety of insulin aspart carried out with NovoMix 30 do not all need to be repeated for Truvelog Mix 30.

What are the risks associated with Truvelog Mix 30?

The safety of Truvelog Mix 30 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 NovoMix 30.

The most common side effects with Truvelog Mix 30 (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 Truvelog Mix 30, see the package leaflet.

Why is Truvelog Mix 30 authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Truvelog Mix 30 has a highly similar structure, purity and biological activity to NovoMix 30 and is distributed in the body in the same way.

All these data were considered sufficient to conclude that Truvelog Mix 30 will behave in the same way as NovoMix 30 in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for NovoMix 30, the benefits of Truvelog Mix 30 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 Truvelog Mix 30?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Truvelog Mix 30 have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Truvelog Mix 30 are continuously monitored. Suspected side effects reported with Truvelog Mix 30 are carefully evaluated and any necessary action taken to protect patients.

Other information about Truvelog Mix 30

Further information on Truvelog Mix 30 can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/truvelog-mix-30.

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