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Semglee (*insulin glargine*)

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

What is Semglee and what is it used for?

Semglee is a medicine used to treat diabetes in patients from 2 years of age. It contains the active substance insulin glargine.

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

How is Semglee used?

Semglee is available in pre-filled disposable pens and can only be obtained with a prescription. It is given by injection under the skin in the belly, the thigh, or the upper arm.

Semglee is used once a day at the same time each day. The dose of Semglee is worked out for each patient and depends on the patient's blood glucose (sugar) level and treatment with other insulin medicines. Semglee can also be used with diabetes medicines taken by mouth in patients who have type 2 diabetes.

Patients can inject themselves with Semglee if they have been trained appropriately.

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

How does Semglee work?

Diabetes is a disease in which the level of blood sugar is high, either because the body cannot produce insulin (type 1 diabetes) or because the body does not make enough insulin or cannot use it effectively (type 2 diabetes). Semglee is a replacement insulin that acts in the same way as the body's own insulin and helps glucose enter cells from the blood. By controlling the level of blood glucose, the symptoms of diabetes are reduced and complications are avoided.

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Insulin glargine, the active substance in Semglee, enters the bloodstream more slowly than human insulin after injection and so it works for longer.

What benefits of Semglee have been shown in studies?

Extensive laboratory studies comparing Semglee with Lantus have shown that insulin glargine in Semglee is highly similar to that in Lantus in terms of chemical structure, purity and biological activity. Additional studies showed that Semglee is absorbed into the body in the same way as the reference medicine, Lantus, and could be considered to act similarly on blood glucose.

Because Semglee is a biosimilar medicine, studies on effectiveness and safety were not needed as these have been well established for insulin glargine. However, a supportive study in 558 patients with type 1 diabetes showed Semglee and Lantus had similar effects. Patients in the study had previously had their level of glycosylated haemoglobin (HbA1c), a substance which indicates how well blood glucose is controlled, brought under control with Lantus; continuing treatment with either Semglee or Lantus for 24 weeks indicated comparable control of HbA1c levels with both, the level changing by an average of 0.14% in patients given Semglee, and 0.11% in those given Lantus.

What are the risks associated with Semglee?

The most common side effect with Semglee (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose). For the full list of side effects and restrictions with Semglee, see the package leaflet.

Why is Semglee authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Semglee has been shown to have a comparable quality, safety and effectiveness to Lantus. Therefore, the Agency's view was that, as for Lantus, the benefit of Semglee outweighs the identified risk and it can be authorised in the EU.

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

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

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

Other information about Semglee

Semglee received a marketing authorisation valid throughout the EU on 23 March 2018.

Further information on Semglee can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 03-2018.