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Toujeo[1] (*insulin glargine*)

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

What is Toujeo and what is it used for?

Toujeo is a medicine used to control blood glucose (sugar) levels in adults and children from 6 years of age who have diabetes and need insulin.

It contains the active substance insulin glargine.

How is Toujeo used?

Toujeo is available as prefilled pens containing a solution for injection of 300 units/ml. It is injected once a day under the skin in the abdominal wall (tummy), the thigh, or the deltoid region (shoulder). The site of injection should be changed with each injection to avoid changes to the skin (such as thickening) that would change the way the insulin is absorbed. The patient's blood glucose should be regularly tested to find the lowest effective dose.

Toujeo 300 units/ml must not be used interchangeably with the lower strength insulin glargine (100 units/ml).

The medicine can only be obtained with a prescription. For more information about using Toujeo, see the package leaflet or contact your doctor or pharmacist.

How does Toujeo work?

Diabetes is a disease in which the body does not produce enough insulin to control the level of blood glucose. Toujeo is a replacement insulin that is very similar to the insulin made by the body.

The active substance in Toujeo, insulin glargine, is slightly different from human insulin. The difference means that it is absorbed more slowly and regularly by the body after an injection, and that it has a long duration of action. The replacement insulin acts in the same way as naturally produced insulin and helps glucose enter cells from the blood. By controlling the level of blood glucose, the symptoms and complications of diabetes are reduced.

[1] Previously known as Optisulin

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What benefits of Toujeo have been shown in studies?

The company submitted studies carried out with insulin glargine 100 units/ml.

In addition, the effects of Toujeo were compared with those of insulin glargine 100 units/ml in 4 studies involving 3,045 adults with either type 1 diabetes (when the pancreas cannot produce insulin) or type 2 diabetes (when the body is unable to use insulin effectively). In these studies, Toujeo 300 units/ml was comparable to insulin glargine (100 units/ml) at controlling blood glucose levels.

Toujeo was also comparable to insulin glargine 100 units/ml at controlling blood glucose levels in a study involving 463 children and adolescents aged 6 to 17 years who had type 1 diabetes.

What are the risks associated with Toujeo?

The most common side effect with Toujeo (seen in more than 1 patient in 10) is hypoglycaemia (low blood glucose levels). Reactions at the site of the injection (redness, pain, itching and swelling) and skin reactions (rash) have been seen more often in children than in adults.

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

Why is Toujeo authorised in the EU?

The European Medicines Agency decided that Toujeo's benefits are greater than its risks and it can be authorised for use in the EU.

The benefits and safety of insulin glargine in controlling blood glucose level are well established and use of Toujeo allows for a smaller volume to be injected compared with standard insulin, which may be important for patients who require large amounts of insulin.

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

The company that markets Toujeo will provide educational material to healthcare professionals aimed particularly at raising awareness that Toujeo contains insulin that is of a higher strength than standard insulin. The company will also produce educational material for patients on how to use Toujeo correctly, which they should receive from their doctor together with suitable training.

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

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

Other information about Toujeo:

Toujeo received a marketing authorisation valid throughout the EU on 27 June 2000.

Further information on Toujeo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Toujeo-previously-Optisulin.

This overview was last updated in 10-2019.