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Trulicity (*dulaglutide*)

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

What is Trulicity and what is it used for?

Trulicity is a medicine used in adults and children from 10 years of age with type 2 diabetes. It is used in addition to appropriate diet and exercise.

Trulicity is used:

- on its own when use of metformin (another medicine for type 2 diabetes) is not recommended;

- as an 'add-on' to other diabetes medicines.

Trulicity contains the active substance dulaglutide.

How is Trulicity used?

Trulicity can only be obtained with a prescription. It is available as prefilled pens containing a solution to be injected under the skin in the abdomen (belly), in the thigh or in the upper arm.

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

How does Trulicity work?

The active substance in Trulicity, dulaglutide, is a 'GLP-1 receptor agonist'. It acts in the same way as GLP-1 (a hormone produced in the gut) by increasing the amount of insulin that the pancreas releases in response to food. This helps to control blood glucose levels and symptoms of type 2 diabetes.

What benefits of Trulicity have been shown in studies?

In adults, the effectiveness of Trulicity has been studied in 5 main studies involving over 4,500 patients with type 2 diabetes. In these studies, Trulicity was compared with placebo (a dummy treatment) or with other diabetes medicines when used alone or as an add-on to various combination treatments. Information from a supportive study sent with the application was also considered.

The main measure of effectiveness was the change in the level of glycosylated haemoglobin (HbA1c), which is the percentage of haemoglobin in the blood that has glucose attached to it. HbA1c gives an

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indication of how well blood glucose is controlled. The patients' HbA1c at baseline ranged from 7.6 to 8.5% and patients were treated for at least 52 weeks.

Trulicity was more effective than metformin at reducing HbA1c levels when used alone, and it was more effective than the diabetes medicines exenatide (given twice daily) or sitagliptin, and at least as good as insulin glargine, when used as add-on to other treatments.

After 26 weeks of treatment, Trulicity reduced HbA1c by between 0.71 and 1.59 percentage points at the lower dose, and by between 0.78 and 1.64 percentage points at the higher dose. This was considered clinically meaningful and there was evidence that HbA1c levels remained low during long-term treatment. About 51% of those given the lower dose and 60% of patients given the higher dose of Trulicity achieved a target HbA1c below 7.0% and this was generally more than the proportion achieving this target with alternative treatments.

A further study in 9,901 adults with type 2 diabetes found Trulicity effective at reducing major harmful effects on the heart and the circulatory system. Stroke, heart attack or death from heart of circulatory problems occurred in 12.0% of patients receiving Trulicity over about 5 years compared with 13.4% of patients receiving placebo.

The benefits of Trulicity were also investigated in one main study involving 154 children from 10 years of age with type 2 diabetes. After 26 weeks of treatment, patients on Trulicity had a reduction in HbA1c levels of 0.7 percentage points, versus an increase of 0.6 percentage points for patients on placebo. This difference between Trulicity and placebo was considered clinically meaningful.

What are the risks associated with Trulicity?

The most common side effects with Trulicity (which may affect more than 1 in 10 people) are nausea (feeling sick), vomiting and diarrhoea. For the full list of side effects and restrictions of Trulicity, see the package leaflet.

Why is Trulicity authorised in the EU?

The European Medicines Agency decided that Trulicity's benefits are greater than its risks and it can be authorised for use in the EU. The medicine was effective for treating type 2 diabetes: it improved control of blood sugar levels in adults and children from 10 years of age and was shown to reduce harmful effects on the heart and blood circulation in adults. In addition, Trulicity has the advantage that it can be given once a week. The medicine's side effects are considered manageable.

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

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

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

Other information about Trulicity

Trulicity received a marketing authorisation valid throughout the EU on 21 November 2014.

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

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