



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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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 diabetes medicine used in adults with type 2 diabetes when the disease is not controlled well enough. It is used with exercise and diet suitable for controlling diabetes.

Trulicity can be used together with other diabetes medicines or it can be used on its own in patients who cannot take metformin.

Trulicity contains the active substance dulaglutide.

### How is Trulicity used?

Trulicity can only be obtained with a prescription. It is available as prefilled pens (0.75 mg and 1.5 mg) containing a solution to be injected under the skin.

Patients inject the medicine themselves (after suitable training) under the skin in the abdomen (belly) or in the thigh. The recommended dose is 0.75 mg injected once a week when used on its own, and 1.5 mg once a week in combination with other diabetes medicines (but doctors may begin with the lower dose in patients at greater risk of side effects). When used with a sulphonylurea (a type of diabetes medicine) or with insulin, the doctor may lower the dose of the sulphonylurea or insulin to avoid hypoglycaemia (low blood sugar levels).

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?

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

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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 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 patients 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 or circulatory problems occurred in 12.0% of patients receiving Trulicity over about 5 years compared with 13.4% of patients receiving placebo.

## **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 and reduced harmful effects on the heart and on circulation. 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](http://ema.europa.eu/medicines/human/EPAR/trulicity).

This overview was last updated in 10-2019.