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EPAR summary for the public

Trulicity

dulaglutide

This is a summary of the European public assessment report (EPAR) for Trulicity. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Trulicity.

For practical information about using Trulicity, patients should read the package leaflet or contact their doctor or pharmacist.

What is Trulicity and what is it used for?

Trulicity is a diabetes medicine used in adults with type 2 diabetes to control their blood glucose (sugar) level.

Trulicity can be used on its own in patients whose blood glucose levels are not satisfactorily controlled on diet and exercise alone and who cannot take metformin (another diabetes medicine).

It can also be used as an 'add-on' to other diabetes medicines, including insulin, when these medicines together with exercise and diet are not providing adequate control of blood glucose.

Trulicity contains the active substance dulaglutide.

How is Trulicity used?

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

Patients inject the medicine themselves (after suitable training) under the skin in the abdomen or 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 (although doctors may begin with the lower dose in patients at potentially greater risk such as those aged over 75). When used in combination

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with a type of diabetes medicine called a sulphonylurea or with insulin, the dose of the sulphonylurea or insulin may need to be lowered to avoid hypoglycaemia (low blood sugar levels).

For further information, see the package leaflet.

How does Trulicity work?

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. The active substance in Trulicity, dulaglutide, is a 'GLP-1 receptor agonist'. It works by attaching to receptors for a substance called glucagon-like peptide 1 (GLP-1), which are found on the surface of the cells in the pancreas and stimulate them to release insulin. When Trulicity is injected, dulaglutide reaches the receptors in the pancreas and activates them. This causes the release of insulin and helps to reduce blood glucose levels and control type 2 diabetes.

What benefits of Trulicity have been shown in studies?

The benefits of Trulicity have 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 sixth study that was submitted during the procedure 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. HbA1c gives an indication of how well the blood glucose is controlled. The patients' average 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 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 to be clinically meaningful and there was evidence that the benefits were maintained 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.

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 all side effects and restrictions with Trulicity, see the package leaflet.

Why is Trulicity approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Trulicity's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee noted that the medicine produces a significant and clinically relevant effect in controlling blood glucose when used with other medicines. The medicine was more effective at weekly doses of 1.5 mg than 0.75 mg. However, when used alone in patients who cannot take metformin, or when used in very elderly patients (aged over 75), the ratio of benefit to risk was greatest at the lower dose. With respect to safety, effects of longer term use and safety in vulnerable groups such as the very elderly would

need to be monitored, but there were no specific areas of major concern and the risks were considered similar to those of other medicines in its class. In addition, Trulicity has the advantage of being given once a week.

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

A risk management plan has been developed to ensure that Trulicity is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Trulicity, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Trulicity

The European Commission granted a marketing authorisation valid throughout the European Union for Trulicity on 21 November 2014.

The full EPAR and risk management plan summary for Trulicity can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Trulicity, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2014.