EMA/259283/2022
EMEA/H/C/002020

Bydureon (*exenatide*)

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

What is Bydureon and what is it used for?

Bydureon is a diabetes medicine used together with other diabetes medicines including long-acting insulin to treat adults and children aged 10 years and above with type 2 diabetes whose blood glucose (sugar) levels are not adequately controlled with the other medicines.

Bydureon contains the active substance exenatide.

How is Bydureon used?

Bydureon is given by injection under the skin once a week on the same day each week in the abdomen (belly), thigh or back of the upper arm. Patients inject themselves once they have been trained.

When adding Bydureon to a sulphonylurea (another type of diabetes medicine), the doctor may need to reduce the dose of the sulphonylurea because there is a risk of hypoglycaemia (low blood glucose levels). When adding Bydureon to insulin, the dose of insulin may also need to be adjusted.

Patients using both Bydureon and insulin should inject the medicines separately.

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

How does Bydureon work?

In type 2 diabetes, the pancreas does not make enough insulin to control the level of glucose in the blood or the body is unable to use insulin effectively. This leads to excess glucose in the blood.

The active substance in Bydureon, exenatide, is an 'incretin mimetic'. This means that it acts in the same way as incretins (hormones produced in the gut) by increasing the amount of insulin released by the pancreas in response to food. This helps to control blood glucose levels.

What benefits of Bydureon have been shown in studies?

Bydureon was effective at controlling blood glucose in six main studies involving nearly 2,700 adult patients with type 2 diabetes. In all of the studies, the main measure of effectiveness was the reduction in the amount of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled.

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The first two studies (in a total of 555 patients) compared Bydureon with another medicine also containing exenatide but given twice daily, both given as add-on treatment to oral diabetes medicines (medicines taken by mouth) or diet and exercise alone. At the start of the studies, the patients' HbA1c levels were around 8.4%. In the first study, Bydureon reduced HbA1c levels by an average of 1.9 percentage points after 30 weeks of treatment, compared with an average reduction of 1.5 points with exenatide given twice daily. In the second study, the average reduction was 1.6 points after 24 weeks of treatment with Bydureon, compared with an average reduction of 0.9 points with exenatide given twice daily.

The third study (in 514 patients) compared Bydureon with the oral diabetes medicines sitagliptin or pioglitazone as add-on treatment to metformin (another diabetes medicine). At the start of the study, the patients' HbA1c levels were around 8.5%. Bydureon reduced HbA1c levels by an average of 1.4 points after 26 weeks of treatment, compared with an average reduction of 0.8 and 1.1 points with sitagliptin and pioglitazone respectively.

The fourth study (in 456 patients) compared Bydureon with insulin glargine (a long-acting insulin) as add-on treatment to metformin with or without a sulphonylurea. At the start of the study, the patients' HbA1c levels were around 8.3%. The average reduction with Bydureon was 1.5 points after 26 weeks, compared with an average reduction of 1.3 points with insulin glargine.

In the fifth study (in 695 patients), Bydureon given with dapagliflozin (an oral diabetes medicine) was compared with Bydureon alone and dapagliflozin alone. All patients were also taking metformin. At the start of the study, the patients' HbA1c levels were around 9.3%. The average reduction with Bydureon plus dapagliflozin was 2.0 points after 28 weeks, compared with an average reduction of 1.6 points with Bydureon alone and 1.4 points with dapagliflozin alone.

In the sixth study (in 464 patients), Bydureon given together with insulin glargine with or without metformin was compared with placebo (a dummy treatment) also given with insulin glargine with or without metformin. At the start of the study, the patients' HbA1c levels were around 8.5%. The average reduction with Bydureon was 1.0 point after 28 weeks, compared with an average reduction of 0.2 points with placebo.

In addition, a study in 83 children with type 2 diabetes aged between 10 and 18 years compared Bydureon with placebo, both given either alone or added to an oral diabetes medicine with or without insulin. At the start of the study, the patients' HbA1c levels were around 8%. The average reduction with Bydureon was 0.4 points after 24 weeks, compared with an average increase of 0.5 points with placebo.

What are the risks associated with Bydureon?

The most common side effects with Bydureon in adults are nausea (feeling sick) and diarrhoea. Nausea occurs mainly at the start of treatment and decreases over time. In addition, reactions at the site of injection (itching and redness), low blood glucose levels (when used with a sulphonylurea) and headache occur. Most side effects are mild to moderate in intensity. The safety profile in children is similar to that in adults. For the full list of side effects and restrictions with Bydureon, see the package leaflet.

Why is Bydureon authorised in the EU?

The European Medicines Agency noted that the benefits of Bydureon, such as its effect on reducing the levels of HbA1c, compare well with those of comparator medicines and that its side effects are manageable. The Agency therefore decided that Bydureon's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Bydureon

Bydureon received a marketing authorisation valid throughout the EU for Bydureon on 17 June 2011.

Further information on Bydureon can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/bydureon

This overview was last updated in 05-2022.