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EPAR summary for the public

Byetta

exenatide

This document is a summary of the European public assessment report (EPAR) for Byetta. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Byetta.

What is Byetta?

Byetta is a solution for injection that contains the active substance exenatide. It is available as prefilled injection pens that provide either 5 or 10 micrograms of exenatide in each dose.

What is Byetta used for?

Byetta is used to treat type 2 diabetes. It is used together with other antidiabetes medicines in patients whose blood glucose (sugar) levels are not adequately controlled with the maximum tolerated doses of the other medicines. It can be used with metformin, sulphonylureas, thiazolidinediones, metformin and a sulphonylurea, or metformin and a thiazolidinedione.

Byetta can also be given to patients taking basal insulin (long-acting insulin such as insulin glargine) with or without metformin and/or pioglitazone (a thiazolidinedione) and whose blood glucose levels are not adequately controlled with these medicines.

The medicine can only be obtained with a prescription.

How is Byetta used?

Byetta is given by injection under the skin of the thigh, the abdomen (tummy) or the upper arm, using the injection pen. The pen has a user manual.

Treatment with Byetta should start at a dose of 5 micrograms twice a day for at least a month. The dose can then be increased to 10 micrograms twice a day. A dose higher than 10 micrograms twice a

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day is not recommended. The first dose of the day is administered within the one hour before the morning meal, and the second dose within the one hour before the evening meal. Byetta should never be given after a meal. When adding Byetta to a sulphonylurea or basal insulin, the doctor may need to reduce the dose of the sulphonylurea or basal insulin because there is a risk of hypoglycaemia (low blood sugar levels). Adding Byetta to metformin or pioglitazone is not associated with this risk.

Patients being treated with Byetta should continue to follow their diet and exercise plans.

How does Byetta 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 Byetta, 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 with the control of blood glucose levels.

How has Byetta been studied?

Byetta has been studied in eight main studies involving a total of around 3,000 patients whose blood glucose was not adequately controlled with other antidiabetes medicines.

In five of the studies, Byetta was compared with placebo (a dummy treatment), as an add-on to metformin (336 patients), sulphonylureas with or without metformin (1,110 patients) or thiazolidinediones with or without metformin (398 patients).

Two further studies compared adding Byetta or an insulin to metformin and sulphonylureas. In one study, Byetta was compared with insulin glargine in 456 patients and in the other study it was compared with biphasic insulin in 483 patients.

In another study involving 259 patients, Byetta was compared with placebo, as an add-on to insulin glargine. Patients were also taking either metformin or pioglitazone, or a combination of both.

In all of the studies, the main measure of effectiveness was the change in the levels of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled. At the start of the studies, the patients' HbA1c levels were around 8.4%.

What benefit has Byetta shown during the studies?

Byetta was more effective than placebo in reducing the levels of HbA1c when used in combination with other antidiabetes medicines. When it was added to metformin and/or sulphonylureas, the 5-microgram dose of Byetta decreased HbA1c levels by an average of 0.59% after 30 weeks, and the 10-microgram dose decreased them by an average of 0.89%. When added to thiazolidinediones with or without metformin, the 10-microgram dose of Byetta reduced HbA1c levels by an average of 0.74% after 16 weeks and 0.84% after 26 weeks. Little or no effect was seen with placebo.

Byetta was as effective as injected insulin. The 10-microgram dose of Byetta decreased HbA1c by an average of 1.13% after 26 weeks, compared with an average of 1.10% with insulin glargine. In the final study, the 10-microgram dose of Byetta decreased HbA1c by an average of 1.01% after 52 weeks, compared with an average of 0.86% with biphasic insulin.

Byetta was more effective than placebo when it was given as add-on to insulin glargine (with or without other antidiabetes medications), as Byetta decreased HbA1c by an average of 1.7% compared with an average of 1.0% in patients taking placebo.

What is the risk associated with Byetta?

In studies, the most common side effects with Byetta (seen in more than 1 patient in 10) were hypoglycaemia (when Byetta was used with sulphonylurea with or without metformin), nausea (feeling sick), vomiting and diarrhoea. For the full list of all side effects reported with Byetta, see the package leaflet.

Byetta must not be used in people who are hypersensitive (allergic) to exenatide or any of the other ingredients.

Why has Byetta been approved?

The CHMP decided that Byetta's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Byetta:

The European Commission granted a marketing authorisation valid throughout the European Union for Byetta on 20 November 2006.

The full EPAR for Byetta 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 Byetta, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2012.