European Medicines Agency

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Apidra
insulin glulisine

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Apidra?
Apidra is a solution for injection that contains the active substance insulin glulisine. It is supplied in vials, cartridges and prefilled disposable pens (OptiSet and SoloStar).

What is Apidra used for?
Apidra is used to treat patients aged six years or over with diabetes, when they need insulin.
The medicine can only be obtained with a prescription.

How is Apidra used?
Apidra is given by injection under the skin in the abdominal wall (tummy), the thigh or the shoulder, or by continuous infusion using an insulin pump. It should be given up to 15 minutes before or just after a meal. The site of injection should be changed with each injection to avoid changes to the skin (such as thickening) that can make the insulin work less well than expected. Patients can inject Apidra under the skin themselves. Apidra can also be injected into a vein, but this can only be done by a doctor or nurse.
The patient's blood glucose (sugar) levels should be regularly tested to find the lowest effective dose. Apidra is a short-acting insulin that is used in combination with intermediate- or long-acting insulins or insulin analogues (modified forms of insulin). It may also be used in combination with antidiabetes medicines taken by mouth.

How does Apidra work?
Diabetes is a disease in which the body does not produce enough insulin to control the level of blood glucose. Apidra is a replacement insulin that is very similar to the insulin made by the body.
The active substance in Apidra, insulin glulisine, is produced by a method known as 'recombinant DNA technology': it is made by a bacterium that has received a gene (DNA), which makes it able to produce insulin glulisine. Insulin glulisine is very slightly different from human insulin. The difference means that insulin glulisine acts more rapidly, and has a shorter duration of action than a short-acting human insulin. The replacement insulin acts in same way as naturally produced insulin and helps glucose enter cells from the blood. By controlling the level of blood glucose, the symptoms and complications of diabetes are reduced.

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How has Apidra been studied?
Apidra, used in combination with a long-acting insulin, has been studied in type 1 diabetes (when the body cannot produce insulin) in two studies involving a total of 1,549 adults and in one study involving 572 children and adolescents aged between four and 17 years.
In type 2 diabetes (when the body is unable to use insulin effectively), Apidra has been studied in one study involving 878 adults. In this study, Apidra was used in combination with an intermediate-acting insulin and antidiabetes medicines taken by mouth.
In all four studies, Apidra was compared with other insulins or insulin analogues (regular human insulin or insulin lispro). The main measure of effectiveness was the change in levels of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled.

What benefit has Apidra shown during the studies?
Blood glucose control with Apidra was at least as effective as that with the comparator insulins. In all of the studies, the change in the level of HbA1c seen with Apidra was similar to that seen with the comparator insulins.
In the first study of adults with type 1 diabetes, there was a decrease of 0.14% (from 7.60% to 7.46%) after six months, and a decrease of 0.14% for insulin lispro. Similar reductions were seen in the second study in adults, which compared Apidra with regular human insulin. In the study in children and adolescents, Apidra and insulin lispro produced similar changes in HbA1c after six months. However, there was not enough information to show whether Apidra was effective in children aged below six years.
In adults with type 2 diabetes, there was a decrease in HbA1c of 0.46% after six months of Apidra, compared with 0.30% for regular human insulin.

What is the risk associated with Apidra?
The most common side effect with Apidra (seen in more than 1 patient in 10) is hypoglycaemia (low blood glucose levels). For the full list of all side effects reported with Apidra, see the Package Leaflet.
Apidra should not be used in people who may be hypersensitive (allergic) to insulin glulisine or any of the other ingredients. It must not be used in patients who already have hypoglycaemia. Apidra doses might need to be adjusted when given with some other medicines that may have an effect on blood glucose levels. The full list is available in the Package Leaflet.

Why has Apidra been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Apidra's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Apidra:
The European Commission granted a marketing authorisation valid throughout the European Union for Apidra to Sanofi-Aventis Deutschland GmbH on 27 September 2004. The marketing authorisation is valid for an unlimited period.

The full EPAR for Apidra can be found here.

This summary was last updated in 12-2009.