



EUROPEAN MEDICINES AGENCY
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EPAR summary for the public

Ryzodeg

insulin degludec / insulin aspart

This is a summary of the European public assessment report (EPAR) for Ryzodeg. 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 Ryzodeg.

What is Ryzodeg?

Ryzodeg is a medicine that contains the active substances insulin degludec and insulin aspart. It is available as a solution for injection in a cartridge (100 units/ml) and in a pre-filled pen (100 units/ml).

What is Ryzodeg used for?

Ryzodeg is used to treat diabetes in adults, adolescents and children from 2 years of age.

The medicine can only be obtained with a prescription.

How is Ryzodeg used?

Ryzodeg is injected once or twice a day, at mealtimes. It is given as an injection under the skin in the abdominal wall (at the front of the waist), upper arm or thigh. The place for injection should be altered with each injection to reduce the risk of developing fatty lumps under the skin that can affect the amount of Ryzodeg absorbed into the blood.

The dose of Ryzodeg is determined individually for each patient. In type 1 diabetes, Ryzodeg is used with rapid-acting insulin, which is injected at other mealtimes.



How does Ryzodeg work?

Diabetes is a disease in which the body does not produce enough insulin to control the level of blood sugar or when the body is unable to use insulin effectively. Ryzodeg is a replacement insulin for the insulin normally made by the body.

The active substances in Ryzodeg, insulin degludec and insulin aspart, are produced by a method known as 'recombinant DNA technology': they are made by a yeast that has received a gene (DNA), which makes the yeast able to produce them.

Insulin degludec and insulin aspart are slightly different from human insulin. The differences mean that insulin degludec is absorbed more slowly by the body. This means it has a long duration of action. Meanwhile, insulin aspart is absorbed faster by the body than human insulin, and therefore it starts to work as soon as it is injected and has a short duration of action.

The replacement insulin acts in the same way as natural insulin, and helps glucose from the blood to enter cells. By controlling the level of blood glucose, the symptoms and complications of diabetes are reduced. Injecting Ryzodeg at a main meal provides long-acting insulin to control blood sugar until the next dose as well as short-acting insulin to help deal with the extra sugar from the meal.

How has Ryzodeg been studied?

Ryzodeg has been studied in one main study involving 548 adults with type 1 diabetes and in four main studies involving 1,866 adults with type 2 diabetes. The studies compared Ryzodeg given at mealtimes with insulin glargine or insulin detemir (long-acting insulins), or with biphasic insulin (an insulin formulation consisting of a mixture of intermediate- and rapid-acting insulin). In the studies in type 1 diabetes, patients also received injections of rapid acting insulin at other mealtimes. In the studies in type 2 diabetes, Ryzodeg was either given alone or in combination with other antidiabetes medicines.

Ryzodeg has also been studied in one main study in 362 children aged between 1 and 17 years with type 1 diabetes. Ryzodeg was given once a day at mealtime with insulin aspart given at other mealtimes and this treatment was compared with treatment comprising insulin detemir given once or twice a day with insulin aspart given at all mealtimes.

All of the studies measured the level of glycosylated haemoglobin (HbA1c), which is the percentage of haemoglobin in the blood attached to glucose. HbA1c gives an indication of how well the blood glucose is controlled. All the studies in adults lasted six months, but one was extended to one year. The study in children lasted 16 weeks.

What benefit has Ryzodeg shown during the studies?

The studies in adults showed that Ryzodeg was at least as effective as long-acting insulins and biphasic insulin in controlling blood glucose levels in patients with type 1 and type 2 diabetes. The reduction in HbA1c levels (in percentage points) was 0.7 in patients with type 1 diabetes and between 1 and 1.7 across the trials in patients with type 2 diabetes. In the study in children, the combined use of Ryzodeg and insulin aspart was at least as effective as insulin detemir and insulin aspart, with average HbA1c reductions of 0.27 and 0.23 percentage points respectively.

What is the risk associated with Ryzodeg?

The most frequently reported side effect during treatment with Ryzodeg is hypoglycaemia (low blood glucose levels).

Why has Ryzodeg been approved?

The CHMP concluded that Ryzodeg is effective in controlling blood glucose levels in adults, adolescents and children aged over 2 years with diabetes. Because the dose requirements in young children may not be stable and because they cannot express symptoms of hypoglycaemia, Ryzodeg is not suitable for children aged under 2 years. The Committee concluded that Ryzodeg is generally safe and its side effects are comparable to those of other insulin analogues. It also noted that in the studies with adults Ryzodeg reduces the risk of hypoglycaemia during the night in patients with type 1 and type 2 diabetes. The CHMP decided that Ryzodeg's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

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

Other information about Ryzodeg

The European Commission granted a marketing authorisation valid throughout the European Union for Ryzodeg on 21 January 2013.

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

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