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Rybelsus (*semaglutide*)

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

What is Rybelsus and what is it used for?

Rybelsus is a medicine used to control blood glucose (sugar) levels in adults whose type 2 diabetes is not controlled well enough. It can be used on its own when metformin (another medicine for diabetes) cannot be used, or in combination with other diabetes medicines. It should be used with an appropriate diet and physical exercise.

Rybelsus contains the active substance semaglutide.

How is Rybelsus used?

Rybelsus is available as tablets to be taken by mouth once a day and can only be obtained with a prescription. Patients should start on the lowest dose, which is increased to a maintenance dose after one month. After at least one month on this dose, the dose can be increased to the next higher dose if needed.

For more information about using Rybelsus, see the package leaflet or contact your doctor or pharmacist.

How does Rybelsus work?

Type 2 diabetes is a disease in which the body does not make enough insulin to control the level of glucose in the blood or when the body cannot use insulin effectively. The result is a high level of glucose in the blood.

The active substance in Rybelsus, semaglutide, is a GLP-1 receptor agonist. It acts in the same way as GLP-1 (a hormone produced in the gut) by increasing the amount of insulin that the pancreas releases in response to food. This helps with the control of blood glucose levels.

What benefits of Rybelsus have been shown in studies?

Rybelsus was effective at controlling blood glucose levels in 7 main studies involving a total of over 5,500 patients with type 2 diabetes.

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Depending on the dose, Rybelsus lowered HbA1c (showing improved blood glucose control) by between 0.6 and 1.4 percentage points. The results compared favourably with those with three other diabetes treatments empagliflozin, sitagliptin or liraglutide, which led to reductions of 0.9, 0.8, 0.9 percentage points, respectively. Rybelsus was also more effective than placebo (a dummy treatment).

In addition to better controlled blood glucose, patients taking Rybelsus had a beneficial reduction in body weight after 6 months. A further study in close to 3,200 patients suggested that Rybelsus may reduce the number of heart attacks and strokes compared to placebo; however, the difference was not statistically significant (it may be due to chance).

What are the risks associated with Rybelsus?

For the full list of side effects and restrictions of Rybelsus, see the package leaflet.

The most common side effects with Rybelsus (which may affect more than 1 in 10 people) include nausea (feeling sick), diarrhoea and low blood sugar levels (when used with insulin or a sulphonylurea).

Why is Rybelsus authorised in the EU?

Rybelsus is effective at controlling blood glucose levels in patients with type 2 diabetes and can also help patients reduce their weight. The most common side effects with Rybelsus affect the digestive system; the side effects are generally manageable and similar to those with an authorised injectable form of semaglutide (Ozempic).

As with the injectable form, there is a risk that Rybelsus could worsen some patients' diabetic retinopathy (damage to the retina in the eye). Patients with this condition will therefore be monitored carefully.

The European Medicines Agency concluded that Rybelsus' 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 Rybelsus?

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

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

Other information about Rybelsus

Rybelsus received a marketing authorisation valid throughout the EU on 3 April 2020.

Further information on Rybelsus can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/rybelsus.

This overview was last updated in 07-2025.