swissmedic

Summary report on authorisation dated 1 June 2026

Rybelsus® (active substance: semaglutide)

Indication extension in Switzerland: 3 February 2026

Tablets for the reduction of the risk of serious cardiovascular events (such as heart attack or stroke) in adults with type 2 diabetes mellitus and pre-existing disease of the cardiovascular system and/or kidneys

About the medicinal product

Rybelsus contains the active substance semaglutide.

It was first authorised by Swissmedic on 24 March 2020 for the treatment of type 2 diabetes mellitus.

Rybelsus can now be used to prevent cardiovascular events (i.e. to reduce the risk of serious cardiovascular events such as heart attack, stroke and the resulting fatalities) in adults with type 2 diabetes mellitus who already have cardiovascular disease and/or chronic kidney disease.

Mode of action

Since semaglutide is structurally similar to the endogenous hormone GLP-1, it is able to imitate GLP-1's functions in the body. For this reason, it is also termed a GLP-1 receptor agonist. GLP-1 regulates blood glucose levels in several ways, including triggering insulin release (insulin reduces blood glucose levels) from the pancreas and decreasing glucagon secretion (glucagon increases blood glucose levels). The mechanisms of action underlying the prevention of cardiovascular events have not yet been fully elucidated. It is presumed that the long-term improvement in blood glucose level and positive effects on other risk factors (reduced blood pressure, body weight and blood lipid values) both make a contribution. Involvement of an anti-inflammatory effect is also being discussed.

Administration

Rybelsus is a prescription-only medicine.

Rybelsus is available as tablets in dosage strengths of 3 mg, 7 mg and 14 mg. The usual starting dose is 3 mg once daily. After at least one month of treatment at 3 mg, the dose can be increased to 7 mg once daily. Rybelsus must be taken on an empty stomach. Food, drinks and other medicines may

only be ingested 30 minutes at the earliest after taking Rybelsus.

Efficacy

The efficacy of Rybelsus in reducing the risk of serious cardiovascular events was investigated in a major clinical trial (SOUL). In this trial, 9,650 adult patients with type 2 diabetes mellitus and pre-existing cardiovascular disease were randomly assigned at a ratio of 1:1 to treatment with either Rybelsus or placebo (dummy drug).

The main criterion for assessing efficacy was the additional time to occurrence of a serious cardiovascular event, including stroke, heart attack or death.

SOUL showed that treatment with Rybelsus lowered the risk of serious cardiovascular events. Patients treated with Rybelsus experienced fewer heart attacks and fewer fatalities due to cardiovascular disease; the incidence of strokes was roughly similar in both treatment groups.

The results of SOUL are supported by similar results from an earlier study (PIONEER 6).

Precautions, undesirable effects, & risks

Rybelsus may not be used in those who are hypersensitive to the active substance or any of the excipients.

Rybelsus should not be used in patients with type 1 diabetes mellitus or to treat diabetic ketoacidosis (a complication of diabetes).

Using Rybelsus in combination with a sulphonylurea (medicinal product for the treatment of type 2 diabetes mellitus) or insulin may increase the risk of hypoglycaemia (low blood glucose). To decrease this risk, a reduction in sulphonylurea or insulin dose should be considered.

Cases of acute pancreatitis (inflammation of the pancreas) have been observed with medicinal products similar to Rybelsus (other GLP-1 receptor agonists). For this reason, Rybelsus should only be used with caution in patients with a history of pancreatitis. If acute pancreatitis is suspected, Rybelsus should be discontinued.

A rapid reduction in blood glucose at the start of treatment can lead to temporary exacerbation of diabetic retinopathy (disease of the retina in the eye caused by diabetes mellitus). However, improved blood glucose control decreases the risk of diabetic retinopathy in the long term.

The most common undesirable effects (affecting 1 in 10 or more users) are functional disorders of the gastrointestinal tract, such as nausea, vomiting and diarrhoea. These generally occur at the start of treatment and subside as treatment progresses.

In patients with kidney disease, it should be remembered that adverse reactions such as nausea, vomiting and diarrhoea may cause loss of fluid which, in rare cases, may further impair kidney function.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Clinical studies prove that Rybelsus reduces the risk of serious cardiovascular events in people with type 2 diabetes mellitus and pre-existing cardiovascular disease and/or chronic kidney disease. The safety profile of Rybelsus in the target population was comparable to the existing profile. No additional safety risks were observed.

Taking all the risks and precautions into account, and based on the available data, the benefits of Rybelsus outweigh the risks. Swissmedic has therefore authorised the medicinal product Rybelsus, containing the active substance semaglutide, for the reduction of the risk of serious cardiovascular events in adults with type 2 diabetes mellitus and a history of cardiovascular disease and/or chronic kidney disease in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Rybelsus®

Information for patients (package leaflet): Information for patients Rybelsus®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.