swissmedic

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Rybelsus® (active substance: semaglutide)

First authorisation in Switzerland: 24.03.2020

Medicine for the treatment of adults with insufficiently controlled type 2 diabetes mellitus

About the medicine

Rybelsus, with the active substance semaglutide, was authorised by Swissmedic on 24 March 2020 for the oral treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise. Rybelsus can be used on its own or in combination with other blood glucose-lowering medicines.

Insulin is a blood glucose-lowering hormone secreted by the pancreas. Type 2 diabetes mellitus is a disease in which the natural blood glucose-lowering effect declines in the body. The result is an elevated blood glucose level. In the long term, this promotes damage to the retina and kidneys as well as increasing the risk of a heart attack or stroke.

Rybelsus, with the active substance semaglutide, helps control the blood glucose level.

Mode of action

Semaglutide, the active substance in Rybelsus, is a small protein molecule that resembles the natural intestinal hormone GLP-1. The effects of the natural hormone GLP-1 include increased insulin release from the pancreas and the reduced release of its antagonist glucagon. Rybelsus mimics this function.

Use

Rybelsus is available as a tablet containing 3 mg, 7 mg or 14 mg of the active substance semaglutide and may be taken only if prescribed by a doctor. The starting dose of Rybelsus is 3 mg once daily in the morning. After 1 month, the dose should be increased to 7 mg once daily. If the blood glucose-lowering effect is not sufficient after at least 1 month of treatment, the dose can be increased to a maximum of 14 mg once daily. To ensure that the body is supplied with enough of the active substance, 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

Rybelsus has been tested in various studies involving over 5,000 patients with type 2 diabetes mellitus. The efficacy was compared with a dummy drug (placebo) and with other blood glucose-lowering active substances (empagliflozin, sitagliptin, liraglutide and dulaglutide). In all studies Rybelsus, with the active substance semaglutide, showed a positive, blood glucose-lowering effect. The treatment with Rybelsus improved the average blood glucose level and the fasting blood glucose level (FBG). Moreover, weight loss was observed in those patients who took Rybelsus. The positive effects were maintained until the end of the studies (78 weeks).

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 or for the treatment of diabetic ketoacidosis (serious metabolic complication of insulin deficiency).

The risk of low blood sugar (hypoglycaemia) can be increased when Rybelsus is used in combination with a sulfonylurea (oral medicine for the treatment of type 2 diabetes mellitus) or insulin. In order to reduce this risk, a reduction in the dose of the sulfonylurea or the insulin should be considered.

Cases of acute inflammation of the pancreas (pancreatitis) have been observed during the use of medicines similar to Rybelsus (GLP-1 receptor agonists). Caution is therefore indicated when Rybelsus is used in patients with a history of pancreatitis. Patients must be informed of the typical symptoms of acute pancreatitis. If acute pancreatitis is suspected, Rybelsus should be discontinued.

The most common side effects associated with the administration of Rybelsus are gastrointestinal disorders (nausea, diarrhoea, vomiting). These mainly occurred at the start of the treatment and usually declined as the treatment progressed.

A rapid reduction in the blood glucose at the start of treatment can lead to a temporary worsening of diabetic retinopathy (disease of the retina in the eye caused by diabetes mellitus). The long-term improvement in blood glucose control decreases the risk of diabetic retinopathy.

Other possible side effects and all precautions and risks are listed in the Patient information (package leaflet) and the Information for healthcare professionals.

Why the medicine has been authorised

Comprehensive studies have shown that the medicine Rybelsus, with the active substance semaglutide, effectively controls blood glucose when used as an adjunct to appropriate diet and exercise. Furthermore, patients who were treated with Rybelsus achieved a significant reduction in weight. These positive effects were maintained for up to 78 weeks (end of the study).

Side effects were mainly associated with the digestive tract (e.g. nausea and vomiting), and declined over time as the treatment continued.

The current data demonstrate a positive benefit-risk profile (the benefits outweigh the risks of Rybelsus). Swissmedic has therefore authorised the medicine Rybelsus, with the active substance semaglutide, for use in Switzerland.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Rybelsus, the Information for healthcare professionals and the Patient information (package leaflet) were not yet available. As soon as the medicine is available in Switzerland, the Information for healthcare professionals and the Patient information will be made available online at the following address:
www.swissmedicinfo.ch

Healthcare professionals (doctors, pharmacists and others) can answer any questions about this medicine.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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.