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Mounjaro® (active substance: tirzepatide)

First authorisation in Switzerland: 2 November 2022

Medicinal product (solution for injection in pre-filled pen) for the treatment of type 2 diabetes mellitus

About the medicinal product

The medicinal product Mounjaro, containing the active substance tirzepatide, is used to treat adults with type 2 diabetes mellitus, in addition to diet and exercise, as monotherapy (if initial treatment with metformin is not possible) or in combination with other drugs that lower blood glucose.

In type 2 diabetes the body cannot sufficiently control blood glucose concentrations, resulting in an elevated blood glucose level. In the long term, this damages the retina and kidneys and increases the risk of a heart attack or stroke.

Mounjaro was authorised as part of the joint initiative of the Access Consortium. This joint initiative is a collaborative project between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA) and Swissmedic. The joint initiative coordinates the assessment of authorisation applications for new active substances that have been submitted in at least two of the five countries.

The authorisation application for Mounjaro was submitted to the drug regulatory authorities in Canada and Switzerland. Each country assessed a part of the application and then shared and discussed the results. At the end of the process, each authority decided on the application independently.

Mode of action

The body can regulate blood glucose levels very precisely through various mechanisms. Hormones, including insulin, GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide), help the body lower blood glucose levels. Insulin is secreted by the pancreas, for example when the blood glucose concentration is elevated, and lowers the glucose level in the blood. The two gut hormones GIP and GLP-1 are released from the cells of the intestinal mucosa and stimulate, among other things, the release of insulin. As a "dual receptor agonist", tirzepatide binds to the same binding sites (receptors) in the body as the two endogenous hormones GIP and GLP-1. Consequently, tirzepatide improves the control of

the blood glucose level via these mechanisms. As well as lowering blood glucose, tirzepatide also causes significant weight loss.

Indication

Mounjaro, containing the active substance tirzepatide, is a prescription-only medicine and is available as a pre-filled pen in the dosage strengths 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg and 15 mg, in each case in 0.5 ml of solution. The pre-filled pen is intended for single use. The usual starting dose is 2.5 mg once weekly. After 4 weeks, the dose is increased to 5 mg. If needed, the dose can be further increased in increments of 2.5 mg, subject to a maximum dose of 15 mg once weekly. Mounjaro is injected under the skin of the abdomen, thigh or upper arm. The injection can be administered at any time of day, with or without meals.

Efficacy

The efficacy of Mounjaro was investigated worldwide in seven studies with 5,119 patients. Five of these studies investigated the effect and safety of Mounjaro at various stages of the disease, i.e. with differing previous treatments. Regardless of the stage of the disease and previous treatment, Mounjaro significantly lowered blood glucose and body weight. In these studies Mounjaro was superior both to a dummy drug (placebo) and other drugs that lower blood glucose.

Precautions, undesirable effects & risks

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

The most common undesirable effects are gastrointestinal problems, including nausea (18%) and diarrhoea (15%).

Since the risk of a low blood glucose level (hypoglycaemia) can be increased particularly during concurrent treatment with a sulphonylurea or insulin, a corresponding adjustment of the dose of the sulphonylurea or the insulin should be considered.

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

Why the medicinal product has been authorised

In patients with type 2 diabetes mellitus, satisfactory blood glucose control typically requires a gradual intensification of the drug treatment. Substances that act independently of the phase of the disease and previous treatment and, at the same time, positively influence typical concomitant cardiovascular illnesses and the kidneys are advantageous. Clinical studies show clear blood glucose-lowering and weight-reducing effects for Mounjaro.

The side effect profile of the dual GIP/GLP-1 receptor agonist tirzepatide is comparable with that of GLP-1 receptor agonists that are already used in the treatment of type 2 diabetes mellitus.

The currently available data show that the benefits of treatment with Mounjaro outweigh the risks. Swissmedic has therefore authorised the medicinal product Mounjaro, containing the active substance tirzepatide, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Mounjaro®

Information for patients (package leaflet): Information for patients Mounjaro®

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 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.