

Summary report on authorisation dated 25 October 2024

Mounjaro[®] (active substance: tirzepatide)

Indication extension in Switzerland: 9 July 2022

Medicinal product (solution for injection in a pre-filled pen) in combination with diet and exercise for weight loss and to support weight control in adults

About the medicinal product

The medicinal product Mounjaro, containing the active substance tirzepatide, can be used in adults as an adjunct to a calorie-reduced diet and increased physical activity for chronic weight management.

Mounjaro is used for weight reduction when the initial body mass index (BMI) is $\geq 30 \text{ kg/m}^2$ (obese) or $> 27 \text{ kg/m}^2$ to $< 30 \text{ kg/m}^2$ (overweight) and at least one weight-related comorbidity is present. Weight-related comorbidities may include hypertension (high blood pressure), dyslipi-

daemia (lipid metabolism disorder), obstructive sleep apnoea (sleep-related breathing disorder), cardiovascular disease, prediabetes, and type 2 diabetes mellitus.

Being overweight or obese is becoming increasingly widespread worldwide and can have a major impact on physical health, as well as on the development of secondary diseases, including cancer.

Swissmedic already approved Mounjaro on 2 November 2022 for the treatment of type 2 diabetes mellitus in adults.

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. GIP and GLP-1 receptors¹ have both been found in brain regions important for appetite regulation. Tirzepatide, the active substance in Mounjaro,

regulates appetite and reduces food intake. In addition, tirzepatide delays gastric emptying (i.e. absorption of sugar from food), stimulates insulin secretion in the pancreas, and reduces secretion of the insulin antagonist (glucagon). Ultimately, this leads to a reduction in body weight, particularly body fat mass.

¹ Receptor: A receptor is a protein or a protein complex located on the surface of, or inside, cells. When a specific substance binds to a receptor, a reaction is triggered in the cell.

Administration

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. Every 4 weeks, the dose may be gradually increased by 2.5 mg, if needed, up to a maximum dose of 15 mg once weekly. Mounjaro is injected into the subcutaneous fatty tissue of the abdomen, thigh, or upper arm. The injection can be administered at any time of day, with or without meals.

Efficacy

The safety and efficacy of Mounjaro for chronic weight management (losing and maintaining weight) in combination with a calorie-reduced diet and increased physical activity was investigated in 2 studies in patients without type 2 diabetes mellitus (SURMOUNT-1) and with type 2 diabetes mellitus (SURMOUNT-2).

The efficacy of Mounjaro was confirmed in studies versus a dummy medication (placebo).

Mounjaro led to a sustained and significant weight loss.

The mean reduction in body weight at the maximum dose (15 mg Mounjaro) in patients without type 2 diabetes mellitus was 22.5%, and 15.7% in those with type 2 diabetes mellitus.

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 in clinical studies in more than 1 in 10 users were gastrointestinal disorders including

nausea, diarrhoea, constipation, and vomiting.

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

The conducted studies show a clear, sustained weight-reducing effect of Mounjaro. The safety profile of Mounjaro is known and no new, serious safety signals emerged in the clinical studies that would have argued against approval of the application.

Swissmedic has therefore approved extension of the indication for the medicinal product Mounjaro, with the active substance tirzepatide, in Switzerland for chronic weight management in addition to a calorie-reduced diet and increased physical activity.

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 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.