swissmedic

Summary report on authorisation dated 17 October 2025

Imcivree® (active substance: setmelanotide)

Authorisation in Switzerland: 23 July 2025

Solution for injection for the treatment of obesity caused by certain genetic conditions and for hunger control in adults and children aged 2 and over with Bardet-Biedl syndrome (BBS) or a deficiency of certain proteins (POMC OR LEPR)

About the medicinal product

Imcivree contains the active substance setmelanotide.

Imcivree is indicated for the treatment of obesity and the control of hunger in patients with genetically confirmed diseases such as Bardet-Biedl syndrome (BBS), pro-opiomelanocortin (POMC) deficiency or leptin receptor (LEPR) deficiency. Imcivree can be used in adults and children aged 2 and over.

Imcivree helps reduce feelings of hunger and promote weight loss by activating certain receptors in the brain which are responsible for the feeling of fullness after eating and for energy consumption.

Since these three genetic conditions – BBS, POMC and LEPR – are rare diseases, Imcivree has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Imcivree has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control.

In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland. The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Imcivree in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency EMA (EMEA/H/C/005089/0000) and has only conducted a limited scientific review.

Since the assessment was based on the assessment report of a foreign partner authority, the preconditions for a full SwissPAR (Swiss Public Assessment Report) and a resulting Summary report on authorisation are not met. Swissmedic refers to the authorisation of the foreign comparator product.

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Imcivree®

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.