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Imcivree (*setmelanotide*)

An overview of Imcivree and why it is authorised in the EU

What is Imcivree and what is it used for?

Imcivree is a medicine used to treat obesity and help control hunger caused by certain genetic conditions that affect how the brain controls feelings of hunger. It is used in adults and children aged 2 years and older with Bardet Biedl syndrome (BBS), and in those who have pro-opiomelanocortin (POMC) deficiency, including proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency, or leptin receptor (LEPR) deficiency resulting from changes (mutations) in both copies of the genes responsible for making POMC, PCSK1 or LEPR.

These conditions are rare, and Imcivree was designated an 'orphan medicine' (a medicine used in rare diseases). Further information on the orphan designations can be found on the European Medicines Agency's website (pro-opiomelanocortin deficiency: 14 July 2016; leptin receptor deficiency: 19 November 2018; Bardet Biedl syndrome: 21 August 2019).

Imcivree contains the active substance setmelanotide.

How is Imcivree used?

Imcivree can only be obtained with a prescription and treatment should be prescribed and supervised by a doctor with expertise in treating obesity caused by genetic conditions.

Imcivree is given once a day as an injection under the skin of the abdomen (belly). After being trained, patients or carers can inject the medicine themselves.

For more information about using Imcivree, see the package leaflet or contact your healthcare provider.

How does Imcivree work?

People with POMC or PCSK1 deficiency have low levels of pro-opiomelanocortin, a substance that is converted into several hormones, including melanocyte-stimulating hormone (MSH). When levels of MSH are low, it can cause a person to not feel full after eating. In people with LEPR deficiency and BBS, the receptor (target) for the hormone leptin does not work properly so signals to the nerves that make the body feel full and control feelings of hunger cannot be sent. People with POMC, PCSK1 and LEPR deficiency and those with BBS feel continuously hungry and quickly put on weight.

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The active substance in Imcivree, setmelanotide, attaches to and activates a receptor called melanocortin receptor 4, which is normally activated through leptin and MSH, promoting a feeling of fullness after eating. By attaching to this receptor directly, Imcivree is expected to reduce excessive food intake and obesity.

What benefits of Imcivree have been shown in studies?

In 2 main studies, Imcivree was shown to be effective at reducing body weight by at least 10% in people with POMC and LEPR deficiency.

The first study was carried out in 10 patients with obesity due to POMC deficiency resulting from mutations in both copies of the genes for either POMC or PCSK1. After one year of treatment, 8 out of 10 people achieved at least a 10% reduction in body weight.

In the second study carried out in 11 patients with obesity due to LEPR deficiency caused by mutations in both copies of the gene for LEPR, 5 people out of 11 achieved at least a 10% reduction in body weight after one year.

The studies also looked at the effects of Imcivree on the feeling of hunger as measured using a questionnaire: the percentage of patients who achieved at least a 25% reduction in hunger scores was 50% in the first study and 73% in the second study.

In a study that included 28 patients aged 12 years or older with BBS, around 36% of patients achieved at least a 10% reduction in body weight after one year of treatment.

Another study involved 12 children aged 2 to 5 years with obesity due to BBS or POMC, PCSK1 or LEPR deficiency. The study looked at the effect of Imcivree on the children's body mass index (BMI; a measure of the patient's weight in relation to their height), using the BMI Z-score which also takes age into account. After one year of treatment, 10 children achieved a decrease in their BMI Z-score of at least 0.2, meaning that they had a treatment effect. In addition, after a year of treatment, BMI scores decreased by an average of 18%; there was a 26% decrease on average in children with POMC, PCSK1 or LEPR deficiency and a 10% decrease on average for patients with BBS.

Imcivree was not compared to another medicine in these studies.

What are the risks associated with Imcivree?

For the full list of side effects and restrictions of Imcivree, see the package leaflet.

The most common side effects with Imcivree (which may affect more than 1 in 10 people) include hyperpigmentation (coloration of the skin), injection site reactions, nausea (feeling sick), and headache.

Why is Imcivree authorised in the EU?

The number of people with BBS, POMC, PCSK1 or LEPR deficiency is extremely small, so the number of people included in the studies was very limited. However, the studies showed that Imcivree helps to reduce bodyweight and feelings of hunger in these patients, although the effect of the medicine seems less pronounced in people with BBS. These benefits are considered meaningful. Imcivree's side effects are manageable and long-term safety is being evaluated in a dedicated study after authorisation.

The European Medicines Agency therefore decided that Imcivree's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Imcivree?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Imcivree have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Imcivree are continuously monitored. Suspected side effects reported with Imcivree are carefully evaluated and any necessary action taken to protect patients.

Other information about Imcivree

Imcivree received a marketing authorisation valid throughout the EU on 16 July 2021.

Further information on Imcivree can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/imcivree.

This overview was last updated in 07-2024.