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Teizeild (*teplizumab*)

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

What is Teizeild and what is it used for?

Teizeild is a diabetes medicine used to treat adults and children from 8 years of age with stage 2 type 1 diabetes. It is used to delay the disease progressing to stage 3.

In type 1 diabetes, the immune system (the body's natural defences) attacks the insulin-producing cells in the pancreas (called beta cells). Insulin is a hormone that regulates the amount of blood glucose (sugar) in the blood. At stage 2 of the disease, blood sugar levels start to increase and become abnormal because the pancreas is no longer able to produce enough insulin. Symptoms normally appear at stage 3, when the pancreas produces even less insulin and treatment with insulin is needed to manage blood glucose levels.

Teizeild contains the active substance teplizumab.

How is Teizeild used?

Teizeld can only be obtained with a prescription. Because serious side effects, such as cytokine release syndrome, may occur (see risks section below), the medicine should be given by a healthcare professional who has access to medical facilities where such side effects can be treated promptly. Cytokine release syndrome is a potentially life-threatening condition that can cause fever, vomiting, shortness of breath, muscle and joint pain, and low blood pressure.

Teizeild is given by infusion (drip) into a vein over at least 30 minutes. It is given once daily for 14 consecutive days. For the first 5 days of treatment with Teizeild, other medicines will be given to help prevent cytokine release syndrome. Treatment with Teizeild may have to be interrupted or stopped if certain side effects occur.

For more information about using Teizeild, see the package leaflet or contact your doctor or pharmacist.

How does Teizeild work?

The exact way that Teizeild works is not yet fully understood. The active substance in Teizeild, teplizumab, is a monoclonal antibody (a type of protein) that has been designed to attach to CD3, a molecule found on the surface of T cells. T cells are immune cells that are involved in the attack on the

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insulin-producing beta cells in the pancreas. By attaching to CD3, teplizumab is thought to change the activity of T cells, which slows the destruction of beta cells, thereby delaying progression of the disease.

What benefits of Teizeild have been shown in studies?

A study involving 76 adults and children from 8 years of age with stage 2 type 1 diabetes showed that Teizeild delayed the onset of stage 3 type 1 diabetes compared with placebo (a dummy treatment). Following a single course of treatment lasting 14 days, the average time to progression to stage 3 was around 50 months for people treated with Teizeild compared with around 25 months for those given placebo.

What are the risks associated with Teizeild?

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

The most common side effects with Teizeild (which may affect more than 1 in 10 people) include lymphopenia (low levels of lymphocytes, a type of white blood cell), leukopenia (low levels of white blood cells), neutropenia (low levels of neutrophils, a type of white blood cell) and rash.

Some side effects can be serious. The most frequent (which may affect up to 1 in 100 people) is cytokine release syndrome.

Why is Teizeild authorised in the EU?

Teizeild was shown to delay the onset of stage 3 type 1 diabetes in adults and children from 8 years of age with stage 2 type 1 diabetes. Although the number of people included in the main study was small, treatment benefits were considered clinically relevant. Although cases of cytokine release syndrome occurred, most side effects were manageable with appropriate measures. The European Medicines Agency therefore decided that Teizeild's benefits are greater than its risks and that it can be authorised for use in the EU.

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

The company that markets Teizeild must provide educational material to healthcare professionals, patients and caregivers containing important information about treatment with the medicine and possible side effects, especially cytokine release syndrome, lymphopenia and severe infections.

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

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

Other information about Teizeild

Teizeild received a marketing authorisation valid throughout the EU on 8 January 2026.

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

This overview was last updated in 12-2025.