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Redemplo (*plozasiran*)

A plain-language overview of Redemplo and why it is authorised in the EU

What is Redemplo and what is it used for?

Redemplo is a medicine used together with a low-fat diet to reduce blood levels of fats called triglycerides in adults with familial chylomicronaemia syndrome (FCS). This inherited condition gives rise to high levels of triglycerides in the blood, which build up in various parts of the body and lead to symptoms including abdominal (belly) pain, deposits of fat under the skin and pancreatitis (inflammation of the pancreas).

FCS is rare, and Redemplo was designated an 'orphan medicine' (a medicine used in rare diseases) on 19 July 2021. Further information on the orphan designation can be found on the EMA website.

Redemplo contains the active substance plozasiran.

How is Redemplo used?

Redemplo can only be obtained with a prescription; treatment should be started and supervised by a doctor experienced in the treatment of patients with FCS.

Redemplo is available as a solution for injection in prefilled syringes. It is injected once every three months under the skin in the abdomen (belly), the front of the thigh or the back of the upper arm. Patients or their carers can inject Redemplo themselves after being trained.

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

How does Redemplo work?

The active substance in Redemplo, plozasiran, is a small interfering RNA (siRNA), a short piece of genetic material produced in a laboratory, which attaches to and blocks the production of APOC3, a protein that slows down the breakdown of fats. By blocking the production of this protein, Redemplo reduces the level of triglycerides in the blood and, as a result, fat accumulation in the body, which is expected to reduce the risk of pancreatitis.

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What benefits of Redemplo have been shown in studies?

Redemplo was shown to be effective at reducing triglycerides levels in the blood in one main study involving 75 adults with FCS. All patients in the study were on a controlled diet in addition to receiving Redemplo or placebo (a dummy treatment); 50 patients received Redemplo, and 25 placebo.

After 10 months of treatment, patients receiving Redemplo had a median reduction in the blood level of triglycerides of around 80% (which means that half the patients had a reduction of 80% or more, and half had a reduction of less than 80%), compared with 17% in those given placebo. This effect, which was observed in both genetically confirmed FCS and FCS confirmed by clinical diagnosis of signs and symptoms, was maintained during the one-year duration of the study and up to at least 18 months. The study also showed that there were significantly fewer cases of acute pancreatitis in patients using Redemplo compared with those given placebo (2 acute pancreatitis events occurred in 2 patients treated with Redemplo, compared with 7 events that occurred in 5 patients who received placebo).

Studies carried out with Redemplo are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Redemplo?

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

The most common side effect with Redemplo (which may affect more than 1 in 10 people) is hyperglycaemia (high blood sugar levels). Other common side effects (which may affect up to 1 in 10 people) include headache, nausea, and reactions at the injection site.

Why is Redemplo authorised in the EU?

Redemplo was shown to significantly reduce blood levels of triglycerides and appears to lower the risk of acute pancreatitis in adults with FCS. Redemplo does not require genetic confirmation of the condition, thus providing a treatment option for more adults with FCS, addressing an unmet medical need in these patients. The medicine was generally well-tolerated, with an acceptable safety profile.

The European Medicines Agency therefore decided that Redemplo'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 Redemplo?

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

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

Other information about Redemplo

Further information on Redemplo, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/redemplo.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 06-2026.