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Tryngolza (*olezarsen*)

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

What is Tryngolza and what is it used for?

Tryngolza is a medicine used together with diet to treat adults with familial chylomicronaemia syndrome (FCS), a genetic condition that gives rise to high levels of fats called triglycerides in the blood. The excess fat builds up in various parts of the body and leads to symptoms including abdominal pain (belly ache), deposits of fat under the skin and pancreatitis (inflammation of the pancreas). Tryngolza is used to treat FCS that has been confirmed by genetic testing.

FCS is rare, and Tryngolza was designated an 'orphan medicine' (a medicine used in rare diseases) on 21 August 2024. Further information on the orphan designation can be found on the EMA website.

Tryngolza contains the active substance olezarsen.

How is Tryngolza used?

Tryngolza can only be obtained with a prescription and is available as a solution for injection in prefilled pens. It is injected once a month 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 Tryngolza themselves once they have been trained.

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

How does Tryngolza work?

The active substance in Tryngolza, olezarsen, is an 'antisense oligonucleotide,' a very short piece of synthetic (man-made) RNA (a type of genetic material). It has been designed to block the production of a protein called apolipoprotein C-III (apoC-III), which slows down the breakdown of fats. By blocking the production of this protein, the medicine reduces the level of triglycerides in the blood and, as a result, fat accumulation in the body.

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What benefits of Tryngolza have been shown in studies?

Tryngolza was shown to be effective at reducing triglycerides levels in the blood in one main study involving 66 adults with FCS. All patients in the study were on a controlled diet in addition to receiving Tryngolza or placebo (a dummy treatment).

After 6 months of treatment, patients receiving Tryngolza had an average reduction in the blood level of triglycerides of 32%, compared with an average increase of 12% in patients given placebo. This effect was maintained and improved after one year of treatment; the study also showed that there were much fewer cases of acute pancreatitis in patients using Tryngolza compared with those using placebo.

What are the risks associated with Tryngolza?

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

The most common side effects with Tryngolza (which may affect more than 1 in 10 people) include erythema (reddening of the skin) at the injection site, headache, joint pain and vomiting.

Why is Tryngolza authorised in the EU?

Tryngolza was shown to reduce blood levels of triglycerides and lower the risk of acute pancreatitis in patients with FCS. The safety of the medicine was considered acceptable, especially the fact that Tryngolza does not seem to affect blood levels of platelets (components that help the blood to clot). Its monthly dosing schedule and improved safety were also considered of benefit to patients with FCS. The European Medicines Agency therefore decided that Tryngolza'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 Tryngolza?

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

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

Other information about Tryngolza

Tryngolza received a marketing authorisation valid throughout the EU on 17 September 2025.

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

This overview was last updated in 09-2025.