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# Teduglutide Viatris (*teduglutide*)

An overview of Teduglutide Viatris and why it is authorised in the EU

## What is Teduglutide Viatris and what is it used for?

Teduglutide Viatris is a medicine for treating short bowel syndrome (or short gut) in adults and children aged 4 months and above.

Short bowel syndrome is a condition in which nutrients and fluids are not properly absorbed by the gut, usually because a large part of the intestine has been surgically removed.

Teduglutide Viatris contains the active substance teduglutide and is a 'generic medicine'. This means that Teduglutide Viatris contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Teduglutide Viatris is Revestive. For more information on generic medicines, see the question-and-answer document here.

## How is Teduglutide Viatris used?

The medicine can only be obtained with a prescription, and treatment should be started under the supervision of a doctor with experience in treating short bowel syndrome.

Teduglutide Viatris is given once a day as an injection under the skin of the abdomen (belly). Patients or their carers can inject the medicines once they have received adequate training. Treatment should be stopped if a benefit is not observed.

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

## How does Teduglutide Viatris work?

The active substance in Teduglutide Viatris, teduglutide, is similar to human glucagon-like peptide 2 (GLP-2), a hormone made in the gut that increases absorption of nutrients from the intestine.

Teduglutide works in a similar way to GLP-2 and increases intestinal absorption by increasing blood flow to and from the gut, reducing the speed at which food passes through the intestine and reducing acid secretions in the stomach which can interfere with absorption. Teduglutide has the advantage of lasting longer than GLP-2 in the body.

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## How has Teduglutide Viatris been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Revestive, and do not need to be repeated for Teduglutide Viatris.

As for every medicine, the company provided studies on the quality of Teduglutide Viatris. There was no need for 'bioequivalence' studies to investigate whether Teduglutide Viatris is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because the composition of Teduglutide Viatris is very similar to the reference medicine and, when given by injection under the skin, the active substance in both products is expected to be absorbed in the same way.

## What are the benefits and risks of Teduglutide Viatris?

Because Teduglutide Viatris is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

## Why is Teduglutide Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Teduglutide Viatris has been shown to be comparable to Revestive. Therefore, the Agency's view was that, as for Revestive, the benefits of Teduglutide Viatris outweigh the identified risks and it can be authorised for use in the EU.

## What measures are being taken to ensure the safe and effective use of Teduglutide Viatris?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Teduglutide Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Revestive also apply to Teduglutide Viatris where appropriate.

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

## Other information about Teduglutide Viatris

Teduglutide Viatris received a marketing authorisation valid throughout the EU on 08 January 2026.

Further information on Teduglutide Viatris can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/teduglutide-viatris. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 12-2025.