LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nilleto
(teduglutide)

SE/H/2661/01/DC

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Summary Public Assessment Report

Nilleto
teduglutide (synthetic)

Powder and solvent for solution for injection, 5 mg

This is a summary of the public assessment report (PAR) for Nilleto. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Nilleto and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance and is available as powder and solvent for solution for injection.

The reference medicine for the product is Revestive.

Nilleto is used to treat adults, children and adolescents (aged 4 months and above) with Short Bowel Syndrome. Short Bowel Syndrome is a disorder arising from an inability to absorb food nutrients and fluid across the gut. It is often caused by surgical removal of all or part of the small intestine.

How does Nilleto work?

Nilleto contains the active substance teduglutide. It improves the absorption of nutrients and fluid from your remaining gastrointestinal tract (gut).

How is Nilleto used?

The pharmaceutical form is Powder and solvent for solution for infusion.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Nilleto have been shown in studies?

Studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Revestive. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Nilleto?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Nilleto approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Revestive, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

For more details, please see the full PAR for Nilleto on the following website: MRI - Home.

Other information about Nilleto

The full PAR for Nilleto can be found on the following website: MRI - Home. For more information about treatment with Nilleto, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-05.