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EPAR summary for the public

Revestive

teduglutide

This is a summary of the European public assessment report (EPAR) for Revestive. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Revestive.

For practical information about using Revestive, patients should read the package leaflet or contact their doctor or pharmacist.

What is Revestive and what is it used for?

Revestive is a medicine for treating short bowel syndrome (or short gut) in adults and children aged 1 year 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.

Because the number of patients with the condition is low, the disease is considered 'rare', and Revestive was designated an 'orphan medicine' (a medicine used in rare diseases) on 11 December 2001.

Revestive contains the active substance teduglutide.

How is Revestive used?

Revestive is given as an injection under the skin of the abdomen. The recommended dose is 0.05 mg per kilogram body weight once a day, with the daily dose reduced by half in patients with moderate or severely reduced kidney function. If a benefit is not observed, treatment should be stopped.

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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. Patients or their carers can inject the medicines once they have received adequate training.

For further information, see the package leaflet.

How does Revestive work?

The active substance in Revestive, 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 and reducing acid secretions in the stomach which can interfere with absorption in the intestine. Teduglutide has the advantage of lasting longer than GLP-2 in the body.

What benefits of Revestive have been shown in studies?

Patients with short bowel syndrome are usually given nutrients as an infusion directly into their veins (parenteral nutrition). Revestive has been shown in 2 studies to reduce the amount of parenteral nutrition that patients need.

In one study in adults, 63% (27 out of 43) of those who received Revestive had their parenteral nutrition at 20 weeks reduced by at least a fifth and maintained this reduced intake at 24 weeks. This compares with 30% (13 out of 43) of those given placebo (a dummy treatment).

In a second study in children, 53% (8 out of 15) of those who received Revestive had their parenteral nutrition at 12 weeks reduced by at least a tenth, while none (0 out of 5) of the patients who received a standard treatment achieved the same.

What are the risks associated with Revestive?

The most commonly reported side effects with Revestive (which may occur in more than 1 in 10 patients) were respiratory tract infections (infections of the throat, sinuses, airways or lungs), headache, belly ache and swollen stomach, nausea, vomiting, and reddening, pain or swelling at the site of the injection. In addition, patients with a stoma (an artificial opening at the front of the abdomen to collect faeces or urine) commonly experienced complications, such as swelling of the stoma.

The majority of these reactions were mild or moderate. For the full list of all side effects reported with Revestive, see the package leaflet.

Revestive must not be used in patients who have, or are suspected to have, cancer. It must not be used in patients who have had a gastrointestinal cancer (cancer of the stomach, gut or liver) in the last five years. For the full list of restrictions, see the package leaflet.

Why is Revestive approved?

Studies show that Revestive is beneficial for patients with short bowel syndrome as it significantly reduces the amount of parenteral nutrition they need. Patients who need high volumes of parenteral nutrition may benefit from a significant reduction, whereas patients in need of low amounts may have the chance to be weaned off completely. Furthermore, Revestive showed an acceptable safety profile.

The CHMP therefore concluded that Revestive's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

The company will provide more data about the medicine's safety from a registry of patients.

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

Other information about Revestive

The European Commission granted a marketing authorisation valid throughout the European Union for Revestive on 30 August 2012.

The full EPAR for Revestive can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Revestive, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Revestive can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 05-2017.