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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 Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Revestive.

What is Revestive?

Revestive is a medicine that contains the active substance teduglutide. It is available as a powder and a solvent to be made up into a solution for injection.

What is Revestive used for?

Revestive is used to treat adults with short bowel syndrome. Short bowel syndrome is a condition in which nutrients and fluids are not properly absorbed by the gut, usually following the surgical removal of a large portion of the small intestine. Revestive is used after 'intestinal adaptation' has occurred (changes in the function of the bowel to compensate for its reduced size following surgery).

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

The medicine can only be obtained with a prescription.

How is Revestive used?

Treatment should be started under the supervision of a doctor with experience in treating short bowel syndrome. At the time of starting treatment with Revestive and regularly during treatment, a specialist should perform a colonoscopy (an examination of the bowel) to find out whether there are polyps (growths) in the large intestine. Any polyps detected before treatment will have to be removed.

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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. The daily dose may be lowered if needed to reduce side effects. The daily dose should be reduced by half in patients with moderate or severely reduced kidney function.

Treatment should be evaluated after six months. If a benefit is not observed, treatment should be stopped.

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 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 is produced by a method known as ‘recombinant DNA technology’: it is made by bacteria which have received a gene (DNA) that makes them able to produce it. Teduglutide has the advantage of lasting longer than GLP-2 in the body.

How has Revestive been studied?

The effects of Revestive were first tested in experimental models before being studied in humans.

Revestive was studied in one main study involving 86 patients with short bowel syndrome due to removal of a large section of the small intestine and who needed parenteral nutrition (nutrients and fluids given directly into a vein) at least three times a week.

In this study, patients received 0.05 mg/kg Revestive or placebo every day for 24 weeks. The main measure of effectiveness was the percentage of patients who responded to treatment. Response to treatment was defined as reaching at least a 20% reduction in the volume of parenteral nutrition at week 20, and maintaining at least a 20% reduction of weekly volume of parenteral nutrition at week 24.

What benefit has Revestive shown during the studies?

In the main study, 62.8% (27 out of 43) of patients who received 0.05 mg/kg of Revestive responded to treatment, compared with 30.2% (13 out of 43) who received placebo.

What is the risk associated with Revestive?

The most commonly reported side effects with Revestive were abdominal pain and distension (aching and swollen stomach, 49%), respiratory tract infections (an infection of the throat, sinuses, airways or lungs 28%), nausea (feeling sick, 27%), reddening, pain or swelling at the site of the injection (21%), headache (17%), vomiting (14%) and oedema peripheral (swelling of hands and/or feet , 10%). Approximately 38% of the treated patients with a stoma (an artificial anus) experienced gastrointestinal stoma complications. 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 are hypersensitive (allergic) to teduglutide or any of the other ingredients. It must not be used in patients who have, or are suspected to have, a 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.

Why has Revestive been approved?

The CHMP considered that Revestive was beneficial for patients with short bowel syndrome as it significantly reduced the amount of parenteral nutrition needed, an effect which was maintained after a year of treatment. 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. The Committee also noted that short bowel syndrome is a serious and disabling condition for which only limited symptomatic treatment exists. Furthermore, Revestive showed an acceptable safety profile for up to one year of treatment. Therefore, the CHMP decided 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 use of Revestive?

Revestive was shown to stimulate the growth of cells in the lining of the gut in experimental models. Although Revestive was not shown to have an effect on initiating tumours, the company will closely monitor the medicine's safety and effectiveness by setting up a registry of patients.

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 07-2012.