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Revestive (*teduglutide*)

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

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 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.

Short bowel syndrome is rare, and Revestive was designated an 'orphan medicine' (a medicine used in rare diseases) on 11 December 2001. Further information on the orphan designation can be found on the EMA website.

Revestive contains the active substance teduglutide.

How is Revestive 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.

Revestive 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 Revestive, see the package leaflet or contact your doctor or pharmacist.

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 the intestine and reducing

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acid secretions in the stomach which can interfere with absorption. 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 three 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.

In a third study in infants aged 4 to 12 months (corrected for gestational age), 60% (3 out of 5) of infants given Revestive had their parenteral nutrition at 24 weeks reduced by at least a fifth, while 20% (1 out of 5) of the infants who received a standard treatment achieved the same.

Additional data in young children suggest that the medicine can be expected to behave in the same way across age groups.

What are the risks associated with Revestive?

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

The most common side effects with Revestive (which may affect more than 1 in 10 people) include belly ache and swollen stomach, respiratory tract infections (infections of the throat, sinuses, airways or lungs), reddening, pain or swelling at the site of injection, nausea, headache and vomiting. 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.

Revestive must not be used in patients who have, or are suspected to have, cancer. It must also not be used in patients who have had a gastrointestinal cancer (cancer of the stomach, gut or liver) in the last five years.

Why is Revestive authorised in the EU?

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, with the majority of side effects being mild to moderate.

The European Medicines Agency therefore decided that Revestive'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 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.

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

Other information about Revestive

Revestive received a marketing authorisation valid throughout the EU on 30 August 2012.

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

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