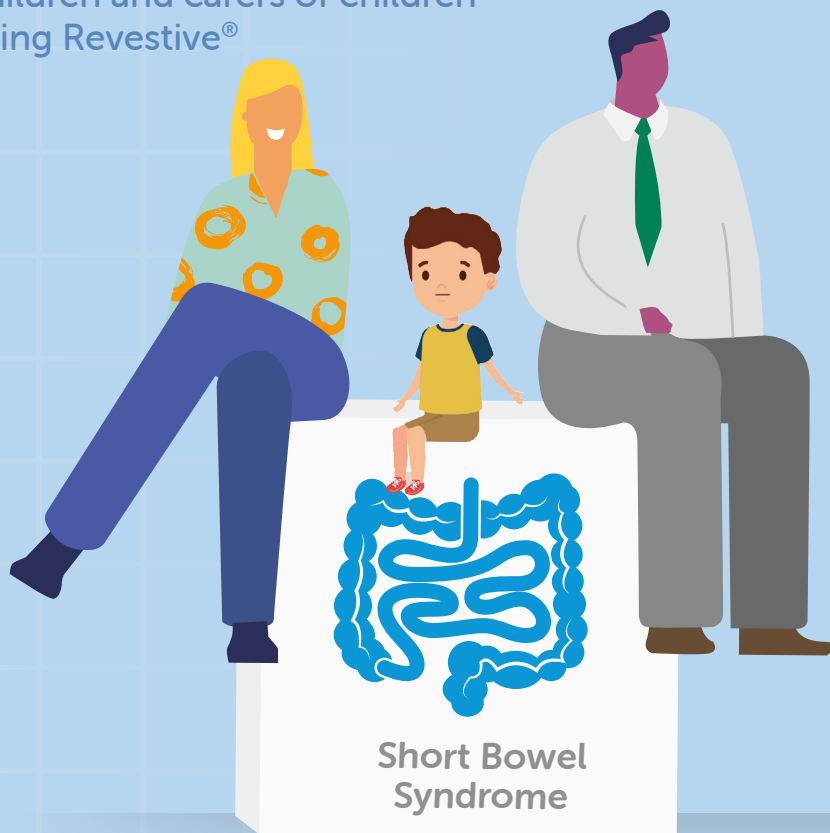


Starting on Revestive[®] ▼ (teduglutide)

For children and carers of children
receiving Revestive[®]



This patient booklet is
provided by



Please ensure you read the Package Leaflet provided in the
Revestive pack before your child starts their treatment

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

Starting on Revestive

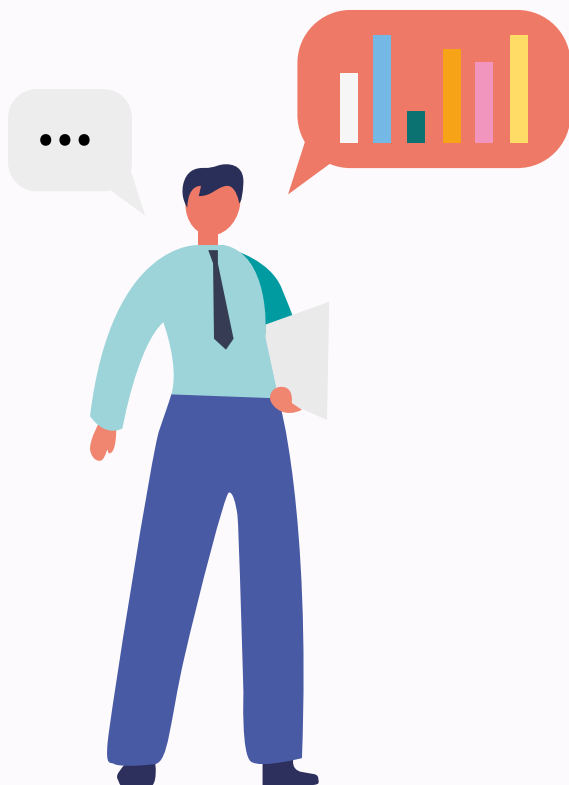
Your child has been prescribed Revestive (teduglutide) by their doctor and you probably have many questions about how this medicine works. You may want to discuss some of these questions with your child's healthcare team, but we hope this brochure also provides some helpful information.

Short bowel syndrome is a disorder arising from an inability to absorb food nutrients and fluid across the gastrointestinal tract (gut). It is often caused by surgical removal of all or part of the small intestine.

Revestive contains the active substance teduglutide. It improves the absorption of nutrients and fluid from the remaining section of the gut.

This brochure provides information on what to expect from your child's treatment with Revestive, and provides relevant information on how you can take an active role in their treatment.

Make sure you also read the Package Leaflet provided in your child's Revestive pack before they start treatment.



Talking about your expectations

Before your child gets started on Revestive, it is important to talk with their healthcare team about what they can realistically expect from their treatment. Keeping track of your child's important health information can help to make sure your child gets the most from their treatment with Revestive.

Taking an active part in your child's treatment programme means sharing your thoughts and concerns and asking questions. Write down a list of any questions or concerns to ask when you next see someone from your healthcare team.

Keep in mind that as Revestive begins to work:

- Your child's intestine should start to absorb more fluid and nutrients, so you may find that over time they have less need for parenteral nutrition
- Your child's diet and medications may be adjusted based on how they respond to Revestive
- You will need to continue to talk with your child's healthcare team about their diet and nutritional needs

Managing your child's treatment

These 4 important steps may help you with your child's treatment:



Know the nutrients and fluids that are best for your child



Understand your child's other medications



Develop a plan on how you could reduce your child's parenteral nutrition intake with your child's healthcare team (if this is your child's treatment goal)



Understand and report any side-effects to their healthcare team

Remember, your child's healthcare team is there to help support you throughout your child's treatment journey.



1. Getting to know your child's nutrients and fluids

To make sure your child gets the nutrients they need and that your child stays appropriately hydrated, work with your child's healthcare team to create a diet plan.

Your child's diet and nutritional needs

- Ask your child's healthcare team if during treatment your child should aim to keep their diet the same or if there are any diet changes you can make to ensure they keep getting the right nutrients

Your child's weight

- Once your child's intestine can absorb more fluids and nutrients, you may start to see changes in your child's weight. Sudden weight gain should be reported to your child's healthcare team. You can use the Patient Diary to help track these and other changes you may notice during treatment
- If you and your child's healthcare team thinks your child needs to gain weight, an oral diet or parental support/enteral feeding may be used to help your child gain more calories

2. Understand your child's other medicines

Your child may be taking other medicines to reduce some of the symptoms related to their short bowel. Talk with your child's healthcare team about any medicines they are taking, and discuss whether the medicines or doses need to be changed over time.

- Revestive helps your child's intestine take more nutrition from the food and fluids they eat and can also increase absorption of oral medicines. Therefore it may be necessary to reduce the doses of your child's other medicines. Your child's healthcare team will advise when or if this is appropriate for you to do so.

3. Why recording information about your child's health status is important

Your child's Patient Diary will help you monitor any changes, chart your child's food and fluids, and let you keep a record of what to discuss with your child's healthcare team at your child's appointments. Here is some information you might want to keep track of:



Medicines they take



Their weight



Their urine output



How much and what they eat and drink



Their stool/ stoma output



How they feel



Their parenteral support/ enteral feeding

You can record this information in your child's Patient Diary every week. This will give you a good picture of their weekly health status and will help you and your child's healthcare team make important decisions about your child's treatment to ensure they get the most from their treatment programme with Revestive. Keeping the Patient Diary also helps you take an active role in your child's treatment.

Did you know?

Filling in your child's weekly status sheets in your child's Patient Diary can help your child's healthcare team know when and how best to reduce their parenteral support if appropriate.

4. Understand, report and manage side effects

All medicines have risks and can possibly cause side effects. It is important to understand these potential effects, so you can recognise them and report them quickly to your child's healthcare team.

Ask your child's healthcare team:

- What side effects to expect
- How you should report them
- How these could be managed

Having a plan to deal with any potential side effects may help lessen their impact on your child's daily life and keep them on track to reach their treatment goals.

Remember, side effects may be very different for different people, and while some people may experience side effects, others may not have any.

For a full list of side effects that your child may experience, please read the Package Leaflet that comes with your child's medicine. Note that some side effects may be related to something other than Revestive treatment, and could be linked with, for example, other medicines they may be taking.



4.1 Know the signs and symptoms of the possible serious side effects of Revestive

Seek immediate medical attention if any of the following serious side effects occur:

Common (may affect up to 1 in 10 people)	Uncommon (may affect up to 1 in 100 people)
<ul style="list-style-type: none">• Congestive heart failure: contact your child’s doctor if they experience tiredness, shortness of breath or swelling of their ankles, legs or face• Inflammation of the pancreas (pancreatitis): contact your child’s doctor or the emergency unit if your child experiences severe stomach ache and fever• Intestinal obstruction (blockage of the bowel): contact your child’s doctor or the emergency unit if your child experiences severe stomach ache, vomiting and constipation• Reduced flow of bile from the gallbladder and/or inflammation of the gallbladder: contact your child’s doctor or the emergency unit if your child experiences yellowing of the skin and the whites in the eyes, itching, dark urine and light-coloured stools or pain in the upper right side or middle of the stomach area	<ul style="list-style-type: none">• Fainting: if your child’s heart rate and breathing is normal and your child awakens fast, speak to your child’s doctor. In other cases, seek medical help as soon as possible

4.2 Why side effects occur

Some side effects of Revestive are related to how the medicine works. They may happen because Revestive may change the structure of the intestine and improve how it absorbs food and fluids.

Your child should not use Revestive if:

- they are allergic to teduglutide or any of the other ingredients of this medicine or trace residues of tetracycline
- they have or are suspected to have cancer
- they have had cancer in the gastrointestinal tract, including liver, gallbladder or bile ducts, and pancreas within the last five years

Before your child starts treatment with Revestive, they will need to have a test done to see if there is blood in the stool. They will also have a colonoscopy done (a procedure to see inside your colon and rectum to check for the presence of polyps (small abnormal growths) and have them removed) if they have unexplained blood in their bowel movements (stools). If polyps are found before their treatment with Revestive, their doctor will decide whether you should use this medicine.

Their doctor will perform further colonoscopies if they continue treatment with Revestive. The doctor will monitor your child's body fluids and electrolytes as an imbalance may cause fluid overload or dehydration.

The doctor will take special care and monitor your child's small bowel function and monitor for signs and symptoms indicating problems with the gallbladder, bile ducts and pancreas.



4.3 Most common side effects

Some of the most commonly reported side effects in patients treated with Revestive are:

Very common (may affect more than 1 in 10 people)	Common (may affect up to 1 in 10 people)
<ul style="list-style-type: none">• Respiratory tract infection (any infection of the sinuses, throat, airways or lungs)• Headache• Stomach pain, bloated stomach, feeling sick (nausea), swelling of stoma (an artificial opening for waste removal), vomiting• Reddening, pain or swelling at the site of the injection	<ul style="list-style-type: none">• Flu (influenza) or flu-like symptoms• Decreased appetite• Swelling of hands and/or feet• Problems sleeping, anxiety,• Cough, shortness of breath• Polyps (small abnormal growths) in their large bowel• Passing gas (flatulence)• Narrowing or blockage of their pancreatic duct, which may cause inflammation of the pancreas• Inflammation of the gallbladder

Reporting side effects

Revestive is subject to additional monitoring. This will allow quick identification of new safety information.

You can help by reporting any side effects your child may get.

If your child gets any side effects, talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.



For more information on how to administer your child's Revestive treatment at home, please follow the link below or scan the QR code:

https://players.brightcove.net/3871979161001/default_default/index.html?videoid=6363692433112

Did you know?

If your child's healthcare team thinks it's right for your child, you can set personal treatment goals and write these down in the back of their Patient Diary.

Bring the Patient Diary with your child's personal treatment goals to all your child's appointments and use your child's diary information to discuss with your child's healthcare team.



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