

REVESTIVE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using REVESTIVE?

REVESTIVE contains the active ingredient teduglutide. REVESTIVE is used to treat adults and children 2 years of age and above with Short Bowel Syndrome who need additional nutrition or fluids from intravenous feeding (parenteral support).

For more information, see Section [1. Why am I using REVESTIVE?](#) in the full CMI.

2. What should I know before I use REVESTIVE?

Do not use if you have ever had an allergic reaction to REVESTIVE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use REVESTIVE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with REVESTIVE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use REVESTIVE?

- The recommended daily dose is 0.05 mg per kg body weight once per day, given under the skin. The dose will be prescribed as mL of solution. Your doctor will choose the dose that is right for you depending on your body weight
- Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section [4. How do I use REVESTIVE?](#) in the full CMI.

5. What should I know while using REVESTIVE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using REVESTIVE. If you become pregnant while using this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop using REVESTIVE or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how REVESTIVE affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep the REVESTIVE in a cool dry place where the temperature stays below 25°C. Do not freeze it. after reconstitution, the solution should be used immediately.

For more information, see Section [5. What should I know while using REVESTIVE?](#) in the full CMI.

6. Are there any side effects?

Common side effects include cold or flu-like symptoms, decreased appetite, headache, stomach pain, bloated stomach, flatulence, nausea, vomiting, swelling of stoma, trouble sleeping, cough, urinary tract infection, reddening, pain or swelling at the site of the injection. Serious side effects include swelling of hands and/or feet; infection of the sinuses, throat, airways or lungs; chest pain; tiredness, shortness of breath, with or without swelling of ankles or legs.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

REVESTIVE®

Active ingredient(s): teduglutide

Consumer Medicine Information (CMI)

This leaflet provides important information about using REVESTIVE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using REVESTIVE.**

Information specific to children are described under the heading "Children". General information for adults are also applicable to children.

The information in this leaflet was last updated in May 2020. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

Where to find information in this leaflet:

- [1. Why am I using REVESTIVE?](#)
- [2. What should I know before I use REVESTIVE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use REVESTIVE?](#)
- [5. What should I know while using REVESTIVE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)
- [8. Instructions for preparing and injecting REVESTIVE](#)

1. Why am I using REVESTIVE?

REVESTIVE contains the active ingredient teduglutide. REVESTIVE improves the absorption of nutrients and fluid from your remaining gut.

REVESTIVE is used to treat adults and children 2 years of age and above with Short Bowel Syndrome who need additional nutrition or fluids from intravenous feeding (parenteral support). 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.

2. What should I know before I use REVESTIVE?

Warnings

Do not use REVESTIVE if you:

- are allergic to teduglutide, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- have or suspected to have cancer.
- have had cancer in the gastrointestinal tract, including liver, gallbladder or bile ducts, and pancreas within the last five years.

Check with your doctor if you:

- have or had any these medical conditions: severely decreased liver function; certain cardiovascular diseases (affecting the heart and/or blood vessels) such as high blood pressure or a weak heart; decreased kidney function; other severe diseases that are not well controlled
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children

REVESTIVE should not be used in children under 2 years of age.

REVESTIVE should not be given for children weighing less than 10 kg.

Medical check-ups for children before and during treatment

- Before starting treatment with this medicine, your child will have a test done to see if there is blood in the stool. Your child will also have a colonoscopy done (a procedure to see inside their 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 treatment with Revestive, the doctor will decide whether your child should use this medicine.
- Revestive should not be used if a cancer is detected during colonoscopy.
- The doctor will perform further colonoscopies if your child continues treatment with Revestive.

Medical check-ups for adults before and during treatment

- If you are an adult, before you start treatment with this medicine, your doctor will need to perform a colonoscopy (a procedure to see inside your colon and rectum) to check for the presence of polyps (small abnormal growths) and remove them. In children and adolescents, the doctor will first check for blood in the stool before they decide to perform a colonoscopy
- It is recommended that your doctor performs these examinations once a year during the first two years after starting treatment, and then at a minimum of five-year intervals. If polyps are found either before or during

your treatment with REVESTIVE, your doctor will decide whether you should continue using this medicine.

- REVESTIVE should not be used if a cancer is detected during your colonoscopy

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

REVESTIVE may affect how other medicines are absorbed from the gut and therefore how well they work. Your doctor may have to change your dose of other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

4. How do I use REVESTIVE?

How much to use

Children (2 years of age and above) and adults

- The recommended daily dose is 0.05 mg per kg body weight once per day, given under the skin. The dose will be prescribed as mL of solution.
- Your doctor will choose the dose that is right for you depending on your body weight. Your doctor will tell you which dose to inject. If you are not sure, ask your doctor, pharmacist or nurse.
- Follow the instructions provided and use REVESTIVE until your doctor tells you to stop.
- It is strongly recommended that every time you/your child receives a dose of REVESTIVE, the name and lot number of the product are recorded in order to maintain a record of the lots used.

When to use REVESTIVE

- REVESTIVE is injected under the skin (subcutaneously) once daily.

How to use REVESTIVE

- The injection can be self-administered or given by another person, for example your doctor, your caregiver or your home nurse.
- If you are self injecting the medicine, you must receive adequate training by your doctor or nurse. You will find detailed instructions for preparing and injecting the medicine at the end of this leaflet.

If you forget to use REVESTIVE

- REVESTIVE should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as possible on that day.
- Never use more than one injection in the same day.
- Do not inject a double dose to make up for the dose that you missed.

If you use too much REVESTIVE

If you think that you have used too much REVESTIVE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre

(by calling 13 11 26 in Australia; 0800 POISON or 0800 764766 in New Zealand), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using REVESTIVE?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using REVESTIVE.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Children

It is recommended that your child's doctor tests for hidden blood in the stool every year while your child is receiving treatment with REVESTIVE. Colonoscopy is recommended for all children after 1 year of treatment and after every 5 years thereafter while on continuous treatment with REVESTIVE, and if they have new or unexplained blood in stool. (See '[Medical check-ups for children before and during treatment](#)' in section 2. What should I know before I use REVESTIVE?

Adult

It is recommended that your doctor performs examinations to check for the presence of polyps once a year during the first two years after starting treatment, and then at a minimum of five-year intervals. (See '[Medical check-ups for adults before and during treatment](#)' in section 2. What should I know before I use REVESTIVE?

Your doctor will take special care and monitor your small bowel function and monitor for signs and symptoms indicating problems with your gallbladder, bile ducts and pancreas.

Remind any doctor or dentist you visit that you are using REVESTIVE.

Things you should not do

- Do not stop using REVESTIVE or lower the dosage without checking with your doctor. If you stop using it suddenly, your fluid balance may change.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how REVESTIVE affects you.

REVESTIVE may cause dizziness in some people. If this happens to you, do not drive or use machines until you feel better.

Looking after your medicine

Store it in a cool dry place where the temperature stays below 25°C. Do not freeze it.

After reconstitution, the solution should be used immediately. However, chemical and physical stability has been demonstrated for 3 hours at 25°C.

Do not store it in the bathroom or near a sink, or in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects. In general, the side effects in children and adolescents are similar to those seen in adults.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> stomach pain nausea bloated stomach vomiting flatulence urinary tract infection cold or flu-like symptoms any infection of the sinuses, throat, airways or lungs decreased appetite headache trouble sleeping, anxiety cough reddening, pain or swelling at the site of the injection swelling of stoma (an artificial opening for waste removal) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> swelling of hands and/or feet any infection of the sinuses, throat, airways or lungs (respiratory tract infection) chest pain fainting tiredness, shortness of breath, with or without swelling of ankles or legs (congestive heart failure) allergic reaction which may result in a rash or more rarely to a sharp drop in blood pressure, difficulty breathing, and hives/itching (anaphylactic reaction) severe stomach ache, fever (inflammation of the pancreas) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> severe stomach ache, vomiting, constipation (blockage of the bowel) 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 (reduced flow of bile from the gallbladder and/or inflammation of the gallbladder) blood in stool (this could be due to small abnormal growth (polyps) in the bowels or stomach) 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What REVESTIVE contains

Active ingredient (main ingredient)	teduglutide
Other ingredients (inactive ingredients)	<p>histidine, mannitol, monobasic sodium phosphate monohydrate, dibasic sodium phosphate heptahydrate.</p> <p>The solvent is sterile water for injections.</p>

Do not take this medicine if you are allergic to any of these ingredients.

What REVESTIVE looks like

REVESTIVE (AUST R 274911) is a powder and solvent for solution for injection (5 mg powder in vial, 0.5 mL solvent in pre-filled syringe). The powder is white and the solvent is clear and colourless.

One vial of powder contains 5 mg of teduglutide. After reconstitution, each vial contains 5 mg teduglutide in 0.5 mL of solution, corresponding to a concentration of 10 mg/mL.

Each pack contains 28 vials with powder and 28 pre-filled syringes with solvent.

Who distributes REVESTIVE

Shire Australia Pty Limited (now part of Takeda)

Level 39, 225 George Street

This leaflet was prepared in May 2020.

8. Instructions for preparing and injecting REVESTIVE

Important information

Please read these instructions before you start using REVESTIVE. If it is your child who is using the medicine, the word 'you' in this leaflet means your child.

REVESTIVE is for injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.

After reconstitution, the solution should be used within 3 hours.

Do not use REVESTIVE if you notice that the solution is cloudy or contains particulate matter.

Dispose of all needles and syringes in a sharps disposal container.

Materials in the REVESTIVE pack:

- 28 vials with 5 mg teduglutide as a powder
- 28 pre-filled syringes with solvent

Materials needed but not included in the REVESTIVE pack:

- reconstitution needles (size 22G, length 1½" (0.7 x 40 mm))
- 1 mL injection syringes (with scale intervals of 0.02 mL or smaller). For children, up to a 1 mL (or smaller) injection syringe (with scale intervals of 0.01mL or smaller) may be used
- thin injection needles for subcutaneous injection (for example, size 26G, length 5/8" (0.45 x 16 mm), or smaller needles for children, as appropriate)
- alcohol wipes
- alcohol swabs
- a puncture-proof container for safe disposal of the used syringes and needles

NOTE: Before you start, make sure you have a clean work surface and that you have washed your hands before proceeding.

1. Prepare the pre-filled syringe

Once you have all the materials ready, you need to prepare the pre-filled syringe. The following procedure shows how you do this.

1.1 Take the pre-filled syringe containing the solvent and flip off the top part of the white plastic cap on the pre-filled syringe so that it is ready for the reconstitution needle to be attached.



1.2 Attach the reconstitution needle (22G, 1½" (0.7 x 40 mm)) to the pre-filled syringe by screwing it on in a clockwise direction.



2. Dissolve the powder

Now you are ready to dissolve the powder with the solvent.

2.1 Remove the green flip-off button from the powder vial, wipe the top with an alcohol wipe and allow it to dry. Do not touch the top of the vial.



2.2 Uncap the reconstitution needle on the pre-filled syringe with solvent without touching the tip of the needle.



2.3 Taking the powder vial, insert the reconstitution needle attached to the pre-filled syringe into the centre of the rubber stopper and gently push the plunger all the way down to inject all the solvent into the vial.

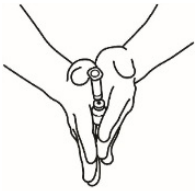


2.4 Leave the reconstitution needle and empty syringe in the vial. Let the vial rest for about 30 seconds.



2.5 Gently roll the vial between your palms for about 15 seconds. Then gently turn the vial upside-down once with the reconstitution needle and empty syringe still in the vial.

Note: Do not shake the vial. Shaking the vial may produce foam, which makes it difficult to extract the solution from the vial.



2.6 Let the vial rest for about 2 minutes.



2.7 Observe the vial for any undissolved powder. If any powder remains, repeat steps 2.5 and 2.6.

Do not shake the vial. If there is still some undissolved powder, discard the vial and start the preparation again from the beginning with a new vial.

NOTE: The final solution should be clear. If the solution is cloudy or contains particulate matter, do not inject it.

NOTE: Once prepared, the solution should be used immediately. It should be kept below 25°C and maximum storage time is 3 hours.

3. Prepare the injection syringe

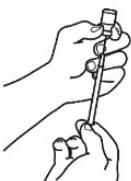
3.1 Remove the reconstitution syringe from the reconstitution needle which is still in the vial and discard the reconstitution syringe.



3.2 Take the injection syringe and attach it to the reconstitution needle which is still in the vial.

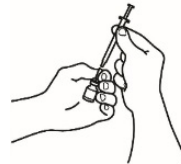


3.3 Turn the vial upside down, slide the tip of the reconstitution needle close to the stopper and allow all the medicine to fill the syringe by pulling the plunger back gently.

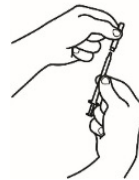


NOTE: If your doctor has told you that you need two vials, prepare a second pre-filled syringe with solvent and a second powder vial as shown in the main steps 1 and 2. Withdraw the solution from the second vial into the same injection syringe by repeating step 3.

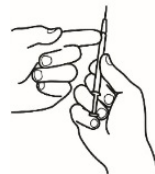
3.4 Remove the injection syringe from the reconstitution needle leaving the needle in the vial. Discard the vial and reconstitution needle together into the sharps disposal container.



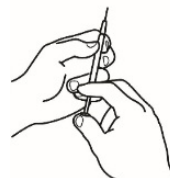
3.5 Take the injection needle (26G, 5/8" (0.45 x 16 mm)), but do not remove the plastic needle cap. Attach the needle to the injection syringe containing the medicine.



3.6 Check for air bubbles. If air bubbles are present, gently tap the syringe until they rise to the top. Then gently push up the plunger to expel the air.



3.7 Your dose in mL has been calculated by your doctor. Expel any excessive volume from the syringe with the needle cap still on until your dose is reached.

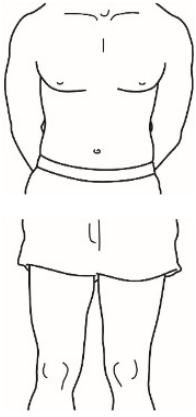


4. Inject the solution

4.1 Find an area on your belly, or if you have pain or hardening of the tissue on your belly, on your thigh where it is easy for you to give the injection.

NOTE: Do not use the same area each day for each injection - rotate sites each day (use upper, lower, and left and right side of your belly) to avoid discomfort. Do not inject into the side if it has a stoma (an artificial opening for waste removal).

Avoid areas that are inflamed, swollen, scarred or covered by a mole, birthmark or other lesion.



4.2 Clean the intended site of injection on your skin with an alcohol swab, using a circular motion, working outwards. Allow the area to air-dry.



4.3 Remove the plastic cap from the needle of the prepared injection syringe. Gently grasp the cleaned skin at the injection site with one hand. With the other hand, hold the syringe as you would with a pencil. Bend your wrist back and quickly insert the needle at a 45° angle.



4.4 Pull back the plunger slightly. If you see any blood in the syringe, withdraw the needle and replace the needle on the injection syringe with a clean one of the same size. You can still use the medicine that is already in the syringe. Try to inject in another place in the cleaned skin area.

4.5 Inject the medicine slowly by pushing steadily on the plunger until all the medicine is injected and the syringe is empty.

4.6 Pull the needle straight out of the skin and discard the needle and syringe together into the sharps disposal container. A small amount of bleeding may occur. If necessary, press gently on the injection site with an alcohol swab or 2x2 gauze until any bleeding has stopped.

4.7 Dispose of all needles and syringes in a sharps disposal container.