

PACKAGE LEAFLET

Package leaflet: Information for the patient

Tidonalle 5 mg powder and solvent for solution for injection teduglutide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Product Name] is and what it is used for
2. What you need to know before you use [Product Name]
3. How to use [Product Name]
4. Possible side effects
5. How to store [Product Name]
6. Contents of the pack and other information

1. What [Product Name] is and what it is used for

[Product Name] contains the active substance teduglutide. It improves the absorption of nutrients and fluid from your remaining gastrointestinal tract (gut).

[Product Name] is used to treat adults, children and adolescents (aged 4 months and above) with Short Bowel Syndrome. Short Bowel Syndrome is a disorder arising from an inability to absorb food nutrients and fluid across the gut. It is often caused by surgical removal of all or part of the small intestine.

2. What you need to know before you use [Product Name]

Do not use [Product Name]

- if you are allergic to teduglutide or any of the other ingredients of this medicine (listed in section 6)
- if you have or are suspected to have cancer.
- if you have had cancer in the gastrointestinal tract, including liver, gallbladder or bile ducts, and pancreas within the last five years.

Warnings and precautions

Talk to your doctor before using [Product Name]:

- if you have severely decreased liver function. Your doctor will consider this when prescribing this medicine.
- if you suffer from certain cardiovascular diseases (affecting the heart and/or blood vessels) such as high blood pressure (hypertension) or have a weak heart (cardiac insufficiency). The signs and symptoms include sudden weight gain, face swelling, swollen ankles and/or shortness of breath.

- if you have other severe diseases that are not well controlled. Your doctor will consider this when prescribing this medicine.
- if you have decreased kidney function. Your doctor may need to give you a lower dose of this medicine.

If you have a hypersensitivity to tetracycline (an antibiotic used to treat infections) your doctor will consider this if there is a plan to change from [Product Name] to an alternative product containing teduglutide. Other teduglutide products might cause a hypersensitivity reaction.

When starting and while getting treated with [Product Name], your doctor may adjust the amount of intravenous fluids or nutrition you receive.

Medical check-ups before and during treatment with [Product Name]

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. It is recommended that your doctor performs these examinations once a year during the first 2 years after starting treatment, and then at a minimum of five-year intervals. If polyps are found either before or during your treatment with [Product Name], your doctor will decide whether you should continue using this medicine. [Product Name] should not be used if a cancer is detected during your colonoscopy. The doctor will monitor your body fluids and electrolytes as an imbalance may cause fluid overload or dehydration.

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.

Children and adolescents

Medical check-ups before and during treatment with [Product Name]

Before you start treatment with this medicine, you will need to have a test done to see if there is blood in the stool. You 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 you have unexplained blood in your bowel movements (stools). If polyps are found before your treatment with [Product Name], your doctor will decide whether you should use this medicine. [Product Name] should not be used if a cancer is detected during your colonoscopy. Your doctor will perform further colonoscopies if you continue treatment with [Product Name]. The doctor will monitor your child's body fluids and electrolytes as an imbalance may cause fluid overload or dehydration.

Children below 4 months of age

This medicine should not be used in children under 4 months of age. This is because there is limited experience with teduglutide in this age group.

Other medicines and [Product Name]

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

[Product Name] 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.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, the use of [Product Name] is not recommended.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before using this medicine.

Driving and using machines

This medicine may cause you to feel dizzy. If this happens to you, do not drive or use machines until you feel better.

Important information about some of the ingredients in [Product Name]

This medicine contains less than 1 mmol sodium (23 mg) per dose. This means that it is essentially 'sodium-free'.

Caution is needed if you are hypersensitive to tetracycline (see “**Do not use [Product Name]**” section).

3. How to use [Product Name]

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Dose

The recommended daily dose is 0.05 mg per kg body weight. The dose will be given in millilitres (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.

Use in children and adolescents

[Product Name] can be used in children and adolescents (aged 4 months and above). Use this medicine exactly as your doctor has told you.

How to use [Product Name]

[Product Name] is injected under the skin (subcutaneously) once daily. The injection can be self-administered or given by another person, for example your doctor, his/her assistant or your home nurse. If you, or your carer, are injecting the medicine, you or your carer must receive adequate training by your doctor or nurse. You will find detailed instructions for injections at the end of this leaflet.

It is strongly recommended that every time you or your child receive a dose of [Product Name], the name and lot number of the product are recorded in order to maintain a record of the lots used.

If you use more [Product Name] than you should

If you inject more [Product Name] than you are told to by your doctor, you should contact your doctor, pharmacist or nurse.

If you forget to use [Product Name]

If you forget to inject this medicine (or cannot inject it at your usual time), use 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 a forgotten dose.

If you stop using [Product Name]

Keep using this medicine for as long as your doctor prescribes it for you. Do not stop using this medicine without consulting your doctor, as a sudden stop can cause changes in your fluid balance.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Common (may affect up to 1 in 10 people):

- Congestive heart failure. Contact your doctor if you experience tiredness, shortness of breath or swelling of ankles or legs or face swelling.
- Inflammation of the pancreas (pancreatitis). Contact your doctor or the emergency unit if you experience severe stomachache and fever
- Intestinal obstruction (blockage of the bowel). Contact your doctor or the emergency unit if you experience severe stomachache, vomiting and constipation
- Reduced flow of bile from the gallbladder and/or inflammation of the gallbladder. Contact your doctor or the emergency unit if you experience 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

Uncommon (may affect up to 1 in 100 people):

- Fainting. If heart rate and breathing is normal and you awaken fast, speak to your doctor. In other cases, seek help as soon as possible

Other side effects include:

Very common (may affect more than 1 in 10 people):

- 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

Common (may affect up to 1 in 10 people):

- 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 your large bowel
- Passing gas (flatulence)
- Narrowing or blockage of your pancreatic duct, which may cause inflammation of the pancreas
- Inflammation of the gallbladder

Uncommon (may affect up to 1 in 100 people)

- Polyps (small abnormal growths) in your small bowel

Not known (frequency cannot be estimated from the available data):

- Allergic reaction (hypersensitivity)
- Fluid retention
- Polyps (small abnormal growths) in your stomach

Use in children and adolescents

In general, the side effects in children and adolescents are similar to those seen in adults.

There is limited experience in children under 4 months of age.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product Name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, the vial and the pre-filled syringe after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C–8°C).

Do not freeze.

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

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Dispose of all needles and syringes in a sharps disposal container.

6. Contents of the pack and other information

What [Product Name] contains

- The active substance is teduglutide. 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.
- The other ingredients are L-histidine, mannitol, sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate heptahydrate
- The solvent contains water for injections.

What [Product Name] looks like and contents of the pack

[Product Name] is a powder and solvent for solution for injection (5 mg teduglutide in vial, 0.5 ml solvent in pre-filled syringe).

The powder is white and the solvent is clear and colourless.

[Product Name] comes in pack sizes of 1 vial of powder with 1 pre-filled syringe or 28 vials of powder with 28 pre-filled syringes.

Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

<This medicine is authorised in the Member States of the European Economic Area <and in the United Kingdom (Northern Ireland)> under the following names:>

<{Name of the Member State}> <{Name of the medicine}>

<{Name of the Member State}> <{Name of the medicine}>

<United Kingdom (Northern Ireland)> <{Name of the medicine}>

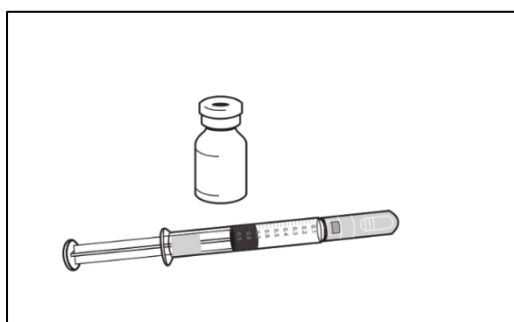
This leaflet was last revised in <{MM/YYYY}><{month YYYY}>.

2026-01-21

Instructions for preparing and injecting [Product Name]

Important information:

- Read the Package Leaflet before using [Product Name].
- [Product Name] is for injection under the skin (subcutaneous injection).
- Do not inject [Product Name] into a vein (intravenously) or muscle (intramuscularly).
- Keep [Product Name] out of the sight and reach of children.
- Do not use [Product Name] after the expiry date which is stated on the carton, the vial and the pre-filled syringe. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C–8°C)
- Do not freeze.
- After reconstitution, from a microbiological point of view, the solution should be used immediately. However, chemical and physical stability has been demonstrated for 3 hours at 25°C.
- Do not use [Product Name] if you notice that the solution is cloudy or contains particulate matter.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- Dispose of all needles and syringes in a sharps disposal container.



Materials provided in the pack:

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

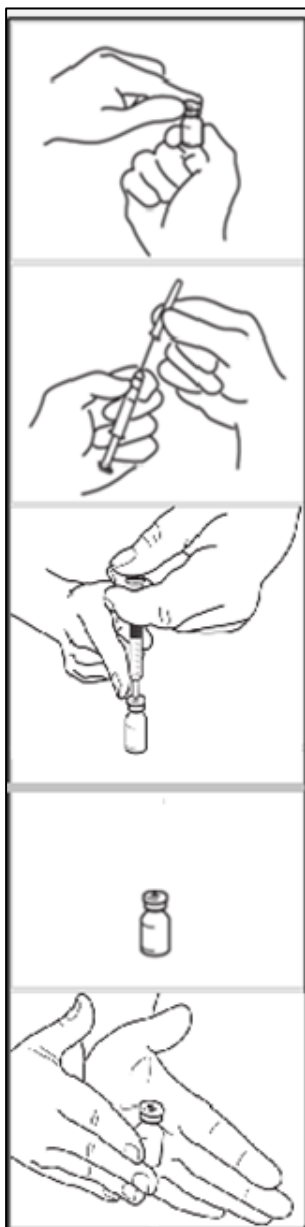
Materials needed but not included in the pack:

- 0.5 or 1 ml injection syringes (with scale intervals of 0.02 ml or smaller). ***For children, a 0.5 ml (or smaller) injection syringe may be used***
- Thin injection needles for subcutaneous injection (e.g., 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. Dissolve the powder

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



1.1 Remove the grey flip-off seal from the powder vial, wipe the top with an alcohol wipe and allow to dry. Do not touch the top of the vial.

1.2 Uncap the rigid needle shield of the pre-filled syringe with solvent without touching the tip of the needle.

1.3 Taking the powder vial, insert the needle of 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. Gently tap the barrel of the diluent syringe with finger. Make sure all the diluent has gone into the teduglutide for injection vial

1.4 Remove the diluent syringe from the teduglutide for injection vial. Let the vial rest for approximately 30 seconds. Do not put the rigid needle shield back on the syringe. Throw away (dispose of) the diluent syringe in your sharps disposal container.

1.5. After 30 seconds, place the teduglutide for injection vial between the palms of your hands. Gently roll the vial for about 15 seconds.

NOTE: Do not shake the teduglutide for injection vial.

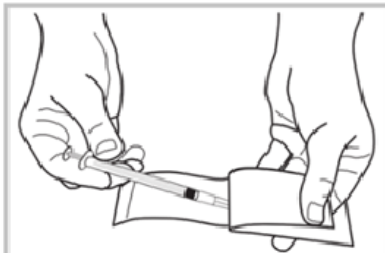
1.6. Do not touch the gray rubber seal. If you do, clean it again with a new alcohol pad. Let the teduglutide for injection vial stand on your work surface for about 2 minutes

1.7. After 2 minutes look at the vial of teduglutide for injection. The liquid in the vial should be clear and colorless to pale yellow, and should not have any particles in it. If there is any powder in the teduglutide for injection vial that did not dissolve, gently roll the vial between your hands for 15 seconds more.

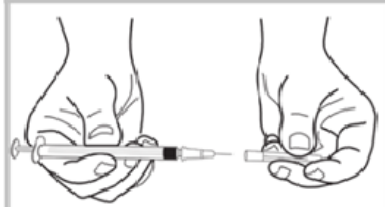
NOTE: Do not shake the teduglutide for injections vial.

NOTE: Check the teduglutide for injection vial again for anything that did not dissolve. Do not use the teduglutide for injection vial if there is anything in it that did not dissolve. Start from the beginning of this instructions to use to prepare a new vial. Use a new teduglutide for injection vial, and a new diluent syringe.

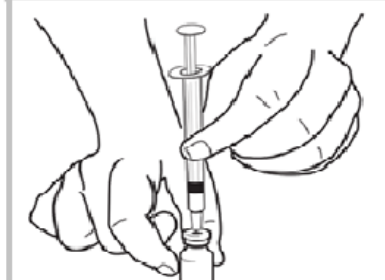
2. Prepare the injection syringe



2.1. Remove the plastic dosing syringe from the package. Use the fold in the package to peel back the plastic cover



2.2. Remove the needle cap from the plastic dosing syringe
Throw the needle cap away. Do not touch the needle or allow it to touch anything.



3.3. Carefully pull back on the plunger to the line that matches the dose prescribed by your healthcare provider.
Use 1 hand to hold the teduglutide for injection vial steady. Use your other hand to insert the needle straight down into the middle of the gray rubber seal on the teduglutide for injection vial.
You may feel some resistance as the needle passes through the rubber seal.



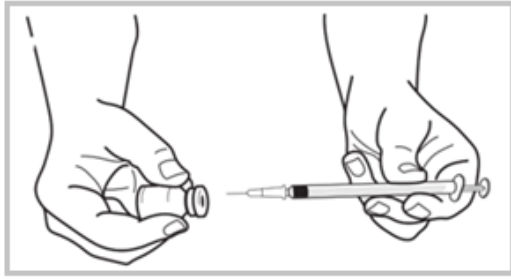
2.4. Gently push down the plunger until all of the air has gone from the plastic dosing syringe into the teduglutide for injection vial.
Turn the teduglutide for injection vial and plastic dosing syringe upside down.



2.5. Hold the teduglutide for injection vial with 1 hand.
Slowly pull back the plunger of the plastic dosing syringe with your other hand.
Fill the plastic dosing syringe until the black tip of the plunger lines up with the mark that matches your prescribed dose.
Keep the plastic dosing syringe and needle in the teduglutide for injection vial.

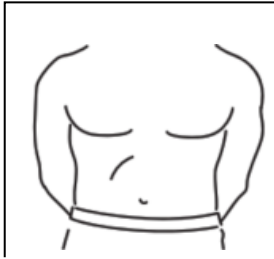


2.6. You may see some bubbles inside the teduglutide for injection vial when the plastic dosing syringe is filled. This is normal. With the needle still in the vial, gently tap the side of the plastic dosing syringe with finger to make any air bubbles rise to the top



2.7. Slowly push the plunger up until all air bubbles are out of the plastic dosing syringe. Make sure the tip of the needle is in the fluid. Slowly pull back the plunger to draw up the right dose of teduglutide for injection into the plastic dosing syringe. Remove the plastic dosing syringe and needle from the teduglutide for injection vial. Do not touch the needle or allow it to touch anything.

3. Inject the solution



3.1. 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 (see the diagram).

NOTE: Do not use the same area each day for each injection - rotate sites (use upper, lower, and left and right side of your belly) to avoid discomfort. Avoid areas that are inflamed, swollen, scarred or covered by a mole, birthmark or other lesion.



3.2. 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.



3.3. 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.

3.4. 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.

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

3.6. 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.

3.7. Dispose all needles and syringes in a sharps disposal container or hard-walled container (for example, a detergent bottle with a lid). This container must be puncture proof (top and sides). If you need a sharps disposal container, please contact your doctor.