



## Your **REVESTIVE**<sup>®\*</sup> Self Administration Guide

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Do not attempt to self-administer unless you have been trained by a healthcare professional.

<sup>Pr</sup> **Revestive**<sup>®</sup>  
teduglutide

# About this medication

## What REVESTIVE® is used for

REVESTIVE (teduglutide for injection) is used to treat adults with short bowel syndrome. Short bowel syndrome (SBS) is a disorder arising from an inability to absorb food, nutrients and fluid across the gastrointestinal tract (gut) due to not enough surface area. It is often caused by surgical removal of all or part of the small intestine.

## How REVESTIVE works

REVESTIVE improves the absorption of fluids from your remaining gut by increasing the surface area and function of your remaining gut.

## How to take REVESTIVE

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

REVESTIVE 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 are injecting the medicine yourself, you must receive adequate training by your doctor or nurse. Do not use the same area each day for each injection. Rotate the site of injection between the upper, lower, left and right side of your belly, either arm or either thigh.

See **Instructions for preparing and injecting REVESTIVE** on following page.

## Usual dose

The recommended daily dose of REVESTIVE is 0.05 mg per kg body weight. The dose will be given in mL of solution.

Your doctor will choose the dose that is right for you depending on your body weight. If you are not sure, ask your doctor, pharmacist or nurse.



# Instructions for preparing and injecting REVESTIVE

## Important information

- / Read the **Patient Medication Information** before using REVESTIVE.
- / REVESTIVE is for injection under the skin (subcutaneous injection) – do not inject into a vein (intravenously) or muscle (intramuscularly).
- / Keep REVESTIVE out of the sight and reach of children.
- / Do not use REVESTIVE 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 below 25°C.
- / Do not freeze.
- / The product should be used within 3 hours after reconstitution.
- / Do not use REVESTIVE 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 after use.



## Materials in the REVESTIVE pack:

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

## Materials needed but not included in the pack:

- / Reconstitution needles (size 22G, length 1-1/2" [0.7 x 40 mm])
- / 1 mL injection syringes (with scale intervals of 0.02 mL or smaller)
- / Thin injection needles for subcutaneous injection (e.g. size 26G, length 5/8" [0.45 x 16 mm])
- / 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.

# Step-by-Step Guide to Injection

## 1. Assemble the pre-filled syringe

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

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



- 1.2 Attach the reconstitution needle (22G, 1-1/2" [0.7 x 40 mm]) to the assembled 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 diluent.

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



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



2.3

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



2.4

Leave the reconstitution needle and empty syringe in the vial. Let the vial rest for approximately 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 two 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:** The product should be used within 3 hours after reconstitution.

### 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 diluent 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 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.



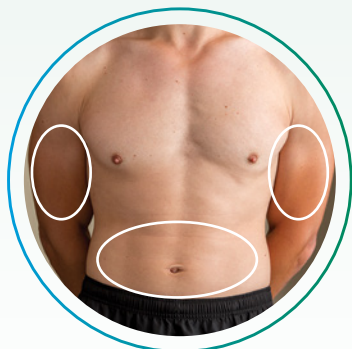
- 3.7 Your dose in mL has been calculated by your doctor. Expel any excessive volume from the syringe with the needle cap still on until your dose is reached.





## 4. Inject the solution

- 4.1 Find an area on your belly, upper arm, or 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 (use upper, lower, and left and right side of your belly, or either arm or thigh) to avoid discomfort. 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 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 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.

## If you miss a dose

If you forget to inject REVESTIVE (or cannot inject it at your usual time), inject it as soon as possible on that day. Never inject more than once in the same day. Do not inject a double dose to make up for a forgotten dose.

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.

## Overdose

If you think you have taken too much REVESTIVE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

# Possible side effects from using REVESTIVE

These are not all the possible side effects you may feel when taking REVESTIVE. If you experience any side effects not listed here, contact your healthcare professional.

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

- / Stomach pain
- / Feeling sick (nausea)
- / Bloated stomach
- / Vomiting
- / Respiratory tract infection (any infection of the sinuses, throat, airways or lungs)
- / Swelling of hands and/or feet
- / Reddening, pain or swelling at the site of the injection
- / Swelling of stoma (an artificial opening for waste removal)

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

- / Passing gas (flatulence)
- / Decreased appetite
- / Problems sleeping
- / Rash (hypersensitivity)
- / Bleeding of the skin
- / Cough

## Serious side effects and what to do about them

### COMMON

#### Symptom/effect

**Reduced flow of bile from the gallbladder and/or inflammation of the gallbladder:** 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

**Congestive heart failure:** Tiredness, shortness of breath or swelling of ankles or legs, sudden weight gain

**Intestinal obstruction (blockage of the bowel):** Stomach ache, vomiting, and constipation

**Inflammation of the pancreas (pancreatitis):** Severe stomach ache and fever

### UNCOMMON

#### Symptom/effect

**Fainting:** If heart rate and breathing are not normal and you don't awaken fast, seek help as soon as possible.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Talk to your healthcare professional in all cases**

## Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- / Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- / Calling toll-free at **1-866-234-2345**.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## How to store REVESTIVE

Do not use this medicine after the expiry date. The expiry date is stated on the carton after EXP.

The expiry date refers to the last day of that month.

The unopened vials may be stored below 25°C.

Do not freeze.

The product should be used within 3 hours after reconstitution.

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

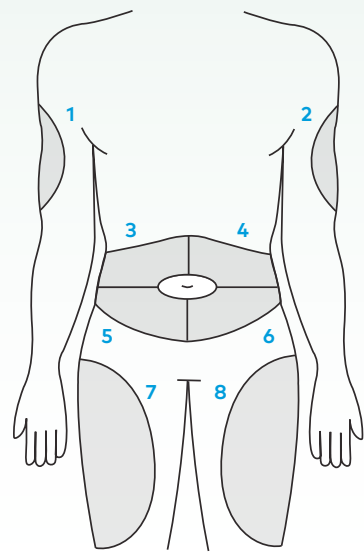
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

Keep out of reach and sight of children.

# Injection Site Log

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



- 1. Right Upper Arm
- 2. Left Upper Arm
- 3. Right Upper Belly
- 4. Left Upper Belly
- 5. Right Lower Belly
- 6. Left Lower Belly
- 7. Right Thigh
- 8. Left Thigh

Date	#	Date	#	Date	#	Date	#

# For more information about REVESTIVE®

If you would like more information about REVESTIVE® talk to your healthcare professional. You may also find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada website at <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php> or by calling 1-844-633-6713.

**Reference:**  
 REVESTIVE\*\* (teduglutide for injection) Product Monograph, Shire Pharmaceuticals Ireland Limited. October 30, 2018.

\* REVESTIVE is a registered trademark of  
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