

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **CABLIVI**®

Caplacizumab for injection, powder for solution

Read this carefully before you start taking **Cablivi** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Cablivi**.

What is Cablivi used for?

Cablivi contains the active substance caplacizumab. It is used to treat an episode of acquired thrombotic thrombocytopenic purpura (aTTP) in adults.

How does Cablivi work?

aTTP is a rare blood clotting disorder in which clots form in small blood vessels. These clots can block blood vessels and damage the brain, heart, kidneys, or other organs. Cablivi prevents the formation of these blood clots by stopping platelets in the blood from clumping together.

What are the ingredients in Cablivi?

Medicinal ingredients: caplacizumab

Non-medicinal ingredients: citric acid anhydrous, polysorbate 80, sucrose, trisodium citrate dihydrate

Cablivi comes in the following dosage forms:

Cablivi comes in a powder vial containing 11 mg of caplacizumab; boxes with 1 or 7 vials

Do not use Cablivi if:

You are allergic to caplacizumab or any of the other ingredients in this medication

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Cablivi. Talk about any health conditions or problems you may have, including if you:

- bleed excessively or experience unusual symptoms such as headache, shortness of breath, tiredness, drop in blood pressure or fainting during treatment. Your doctor may ask you to stop the treatment. The doctor will let you know when you can start your treatment again
- are using anticoagulants (blood thinners) such as vitamin K antagonists, rivaroxaban, apixaban (which treat blood clots). Your doctor will decide how you should be treated
- are using anti-platelet medicines such as aspirin, or low molecular weight heparin (which prevent blood clots). Your doctor will decide how you should be treated

- have a bleeding disorder such as hemophilia. Your doctor will decide how you should be treated
- have severely reduced liver function. Your doctor will decide how you should be treated
- are going to have an operation, dental treatment or other procedures that required incisions. Your doctor will decide if it can be postponed or if you should stop Cablivi before your surgery or dental treatment
- are going to fully or temporarily stop taking Cablivi. There may be a risk of relapse of aTTP especially within 14 days after discontinuation of Cablivi treatment. Therefore, you should inform your doctor before you stop taking Cablivi and follow your doctor's instructions.

Other warnings you should know about:

Pregnancy and/or breastfeeding

Use of Cablivi is not recommended during pregnancy. If you are pregnant or planning to become pregnant, talk to your doctor about using Cablivi. Use of Cablivi is not recommended during breastfeeding. If you are breastfeeding or planning to breastfeed, talk to your doctor about using Cablivi.

Children and adolescents

Cablivi is not recommended for children under 18 years.

Cautions on driving and using machinery

Cablivi is not expected to influence the ability to drive or use machines. However, Cablivi-induced bleeding episodes may result in fatigue that could impair the ability to operate or drive machinery

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Cablivi:

Also tell your doctor if you are using an anticoagulant (blood thinner) medicine such as vitamin K antagonists, rivaroxaban, or apixaban which treat blood clots or anti-platelet agents, such as aspirin, or low molecular weight heparin which prevent blood clots.

How to take Cablivi:

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

First Dose:

- 1 vial injected into a vein by a healthcare professional
- the medicine will be given before starting plasma exchange

Subsequent Doses (see INSTRUCTIONS FOR USE):

- 1 vial once daily as a subcutaneous injection (under the skin of the belly)
- the subcutaneous injection will be given after each daily plasma exchange
- after the daily plasma exchange finishes, your treatment with Cablivi will continue for at least

30 days with injection of 1 vial once daily.

- your doctor may ask you to continue daily treatment for up to additional 28 days
- follow your doctor's instruction after stopping Cablivi.

The first injection of Cablivi into your vein must be given by a healthcare professional. Your doctor may decide that you or your caregiver may inject Cablivi. In this case, your doctor or healthcare provider will train you or your caregiver on how to use Cablivi. Do not try to inject Cablivi until you have been taught how to do so by a healthcare professional. Never use the kit for another injection. Follow the details INSTRUCTIONS FOR USE that are included in each package.

Overdose:

If you think you, or a person you are caring for, have taken too much Cablivi, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is important that you take Cablivi every day as directed by your doctor. If you miss a dose of Cablivi during the plasma exchange period, it should be giving as soon as possible

If a dose of Cablivi is missed after the plasma exchange period, it can be taken within 12 hours of the scheduled dose time. Beyond 12 hours, the missed dose should be skipped, and the next daily dose taken according to the usual dosing schedule.

What are possible side effects from using Cablivi?

These are not all the possible side effects you may have when taking Cablivi. If you experience any side effects not listed here, tell your healthcare professional.

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

- bleeding gums
- fever
- tiredness
- headache
- nosebleeds
- hives

Common (may affect up to 1 in 10 people)

- bruises on the abdomen
- rectal bleeding
- injection site reactions (for example, itching and bleeding)
- muscle pain
- blood in urine
- excessive bleeding during periods
- vaginal bleeding
- shortness of breath

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

- redness in the area where injection is given
- bleeding that may be serious or life-threatening

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Nosebleeds	√		
COMMON			
Excessive bleeding during periods	√		

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

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.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.

Storage:

Cablivi should not be used after the expiry date which is stated on the label and carton.

Cablivi should be stored in a refrigerator (2°C to 8°C) in its original package to protect from light.

Cablivi may be stored at a temperature up to 30°C for a single period of up to 2 months, but not beyond the expiry date. Do not return Cablivi to refrigerated storage after storage at room temperature.

Use the mixed Cablivi solution immediately. The mixed Cablivi solution can be stored for up to 4 hours in the refrigerator at 2°C to 8°C.

Keep out of reach and sight of children.

If you want more information about Cablivi:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website the sanofi-aventis Canada website www.sanofi.com, or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last Revised: May 3, 2022

INSTRUCTIONS FOR USE

Pr CABLIVI[®] Caplacizumab for injection, powder for solution

Read the Instructions for Use before using Cablivi.

Keep these instructions for future use. If you have any further questions, you should ask your health care professional or call 1-800-265-7927.

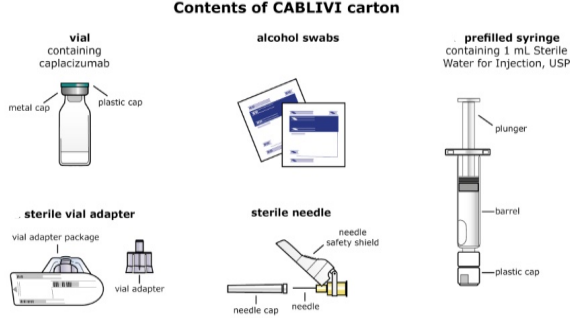
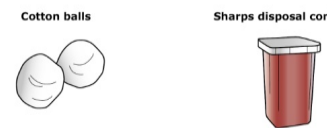
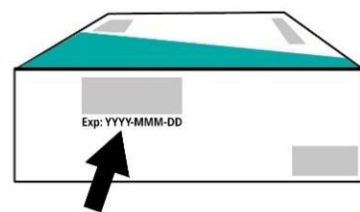
Important Information:

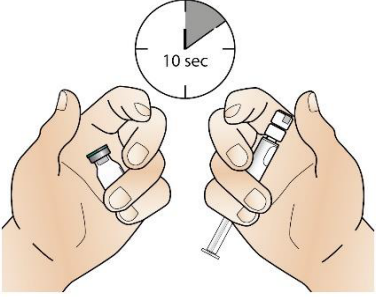
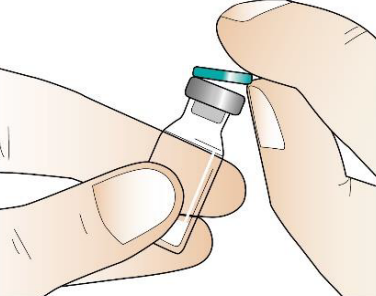

- Make sure the name Cablivi appears on the carton and vial label.
- For each injection, one Cablivi vial is needed. Only use the vial one time.
- Only use the supplies that are provided in the carton to prepare your prescribed dose.
- Do not use Cablivi after the expiration date on the carton.

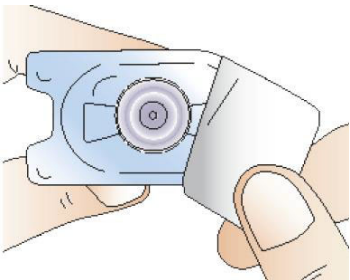
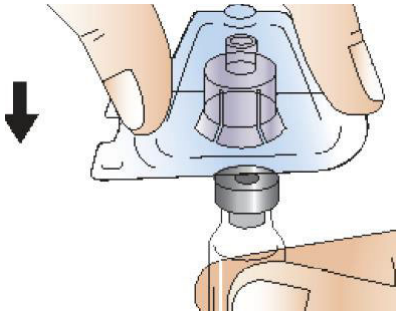
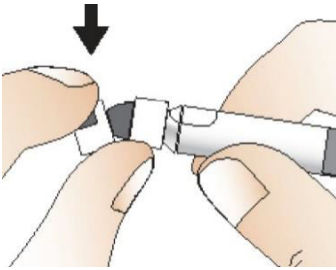
Do not reuse any of the supplies. After your injection, throw away (dispose of) the used vial with any remaining Cablivi liquid in it. Throw away (dispose of) the used vial with the adapter attached and the syringe with the needle attached in a sharps disposal container. See “Step 13: Throw away (dispose of) the used syringe and vial” at the end of this INSTRUCTIONS FOR USE for more disposal information.

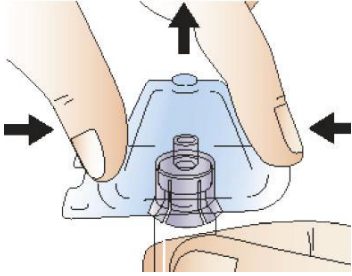
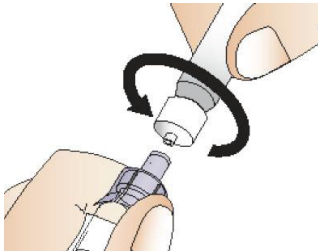
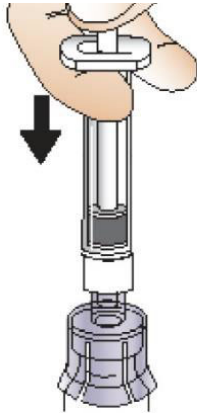
How do I Store Cablivi?


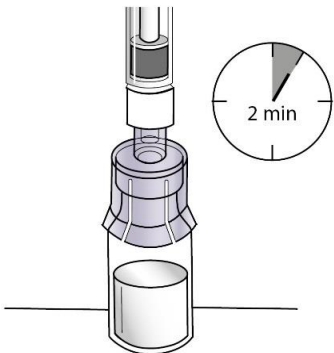
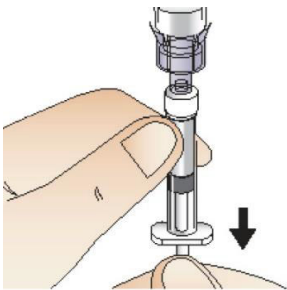
- Store Cablivi in the refrigerator between 2°C to 8°C.
- Used the mixed Cablivi solution immediately. The mixed Cablivi solution can be stored for up to 4 hours in the refrigerator at 2°C to 8°C.
- Cablivi may be stored at a temperature up to 30°C for a single period of up to 2 months, but not beyond the expiry date. Do not return Cablivi to the refrigerator after it has been stored at room temperature.
- Do not freeze.
- Store in original package to protect from light.
- Keep out of reach and sight of children.

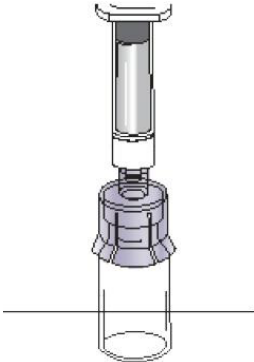

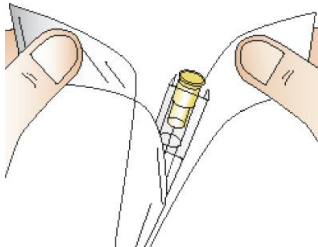
INSTRUCTIONS	RELATED IMAGE		
<p>Each Cablivi carton contains either of the following:</p>			
<table border="0"> <tr> <td data-bbox="175 432 451 947"> <p>Single vial Pack</p> <ul style="list-style-type: none"> • 1 vial of Cablivi • 1 prefilled syringe containing 1 mL Sterile Water for Injection (diluent for Cablivi) • 1 sterile vial adapter • 1 sterile needle • 2 alcohol swabs </td> <td data-bbox="451 432 740 947"> <p>Multi-vial Pack</p> <ul style="list-style-type: none"> • 7 vials of Cablivi • 7 prefilled syringes containing 1 mL Sterile Water for Injection (diluent for Cablivi) • 7 sterile vial adapters • 7 sterile needles • 14 alcohol swabs </td> </tr> </table>	<p>Single vial Pack</p> <ul style="list-style-type: none"> • 1 vial of Cablivi • 1 prefilled syringe containing 1 mL Sterile Water for Injection (diluent for Cablivi) • 1 sterile vial adapter • 1 sterile needle • 2 alcohol swabs 	<p>Multi-vial Pack</p> <ul style="list-style-type: none"> • 7 vials of Cablivi • 7 prefilled syringes containing 1 mL Sterile Water for Injection (diluent for Cablivi) • 7 sterile vial adapters • 7 sterile needles • 14 alcohol swabs 	<p style="text-align: center;">Contents of CABLIVI carton</p>  <p style="text-align: center;">Additional supplies needed (not in CABLIVI carton)</p> 
<p>Single vial Pack</p> <ul style="list-style-type: none"> • 1 vial of Cablivi • 1 prefilled syringe containing 1 mL Sterile Water for Injection (diluent for Cablivi) • 1 sterile vial adapter • 1 sterile needle • 2 alcohol swabs 	<p>Multi-vial Pack</p> <ul style="list-style-type: none"> • 7 vials of Cablivi • 7 prefilled syringes containing 1 mL Sterile Water for Injection (diluent for Cablivi) • 7 sterile vial adapters • 7 sterile needles • 14 alcohol swabs 		
<ul style="list-style-type: none"> • Additional supplies needed: <ul style="list-style-type: none"> • Sharps disposal container (see “step 13: throw away (dispose of) the used syringe” at the end of this Instructions for Use for more disposal information. • Cotton balls 			
<p>Before preparing a dose of Cablivi</p> <ul style="list-style-type: none"> • Wash your hands well with soap and water • Prepare a clean flat surface • Check to make sure the carton contains all of the items needed to prepare a dose • Check the expiration date (see Figure A). Do not use Cablivi if the date has passed • Do not use Cablivi if the packaging or any supplies inside of the carton are damaged in anyway 	 <p style="text-align: center;">Figure A</p>		

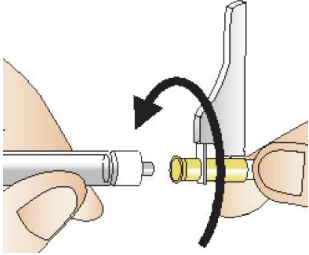
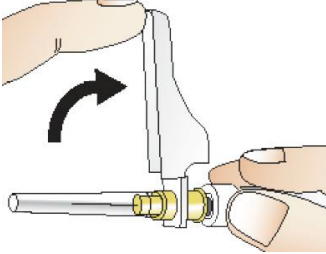
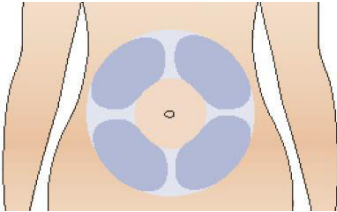
INSTRUCTIONS	RELATED IMAGE
<p>Step 1: Bring the vial and syringe to room temperature</p> <ul style="list-style-type: none"> Place all the supplies in the carton on the clean flat surface If the carton was not stored at room temperature, allow the vial and the syringe to reach room temperature by holding them in your hands for 10 seconds (See Figure B). Do not use any other way to warm up the vial and syringe. 	 <p style="text-align: center;">Figure B</p>
<p>Step 2: Clean the rubber stopper</p> <ul style="list-style-type: none"> Remove the green plastic cap from the metal cap of the vial (See Figure C). Do not use the vial if the green plastic cap is missing. 	 <p style="text-align: center;">Figure C</p>
<ul style="list-style-type: none"> Clean the exposed rubber stopper using one alcohol swab to wipe it and allow it to dry for a few seconds (See Figure D). After cleaning the rubber stopper, do not touch it or allow it to touch any surface. 	 <p style="text-align: center;">Figure D</p>

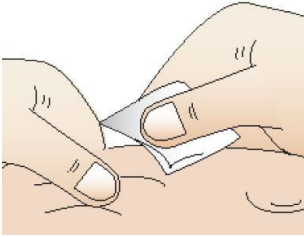
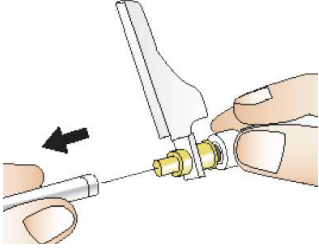
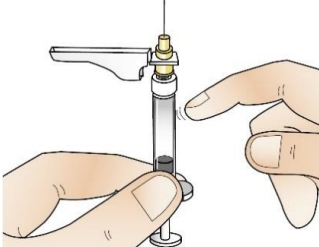
INSTRUCTIONS	RELATED IMAGE
<p>Step 3: Attach the vial adapter</p> <ul style="list-style-type: none"> Take the vial adapter and remove the paper cover (See Figure E). Leave the vial adapter in its opened plastic packaging for now. Do not touch the adapter itself. Place the adapter over the vial, while keeping the adapter in its plastic packaging. 	 <p style="text-align: center;">Figure E</p>
<ul style="list-style-type: none"> Press down firmly on the adapter until it snaps into place, with the adapter spike pushing through the vial stopper (See Figure F). Do not remove the adapter from the vial once attached. Keep the adapter in its plastic packaging. 	 <p style="text-align: center;">Figure F</p>
<p>Step 4: Prepare the syringe</p> <ul style="list-style-type: none"> Pick up the syringe. While holding the syringe with one hand, break off the white plastic cap by snapping at the perforation of the cap with your other hand (See Figure G). Do not use the syringe if the white plastic cap is missing, loose, or damaged. Do not touch the syringe tip or allow it to come into contact with any surfaces. Lay the syringe on the clean flat surface. 	 <p style="text-align: center;">Figure G</p>

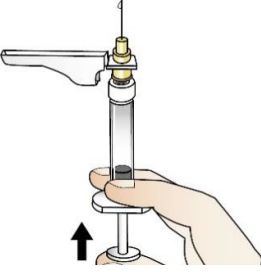
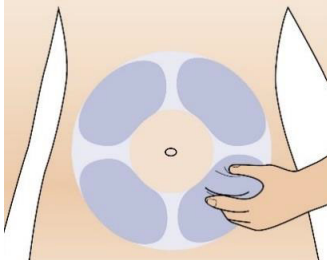
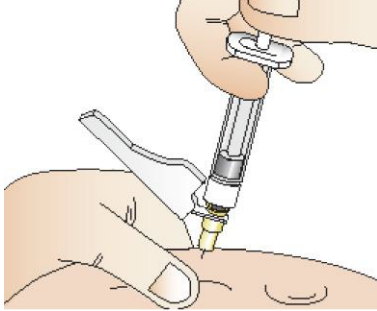
INSTRUCTIONS	RELATED IMAGE
<p>Step 5: Connect the syringe to adapter and vial</p> <ul style="list-style-type: none"> Remove the plastic packaging from the adapter attached to the vial by holding the vial with one hand, pressing the sides of the adapter packaging with your other hand, and then lifting the packaging upwards (See Figure H). Be sure that the adapter does not detach from the vial. 	 <p style="text-align: center;">Figure H</p>
<ul style="list-style-type: none"> Hold the adapter with the attached vial with one hand. Place the tip of the syringe on the connector part of the vial adapter using the other hand. Gently lock the syringe into the vial adapter by turning it clockwise until it cannot twist any further (See Figure I). 	 <p style="text-align: center;">Figure I</p>
<p>Step 6: Prepare the solution</p> <ul style="list-style-type: none"> Place the vial upright on the flat surface with the syringe pointing downwards. Slowly push the syringe plunger down until the syringe is empty (See Figure J). Do not remove the syringe from the vial adapter. 	 <p style="text-align: center;">Figure J</p>

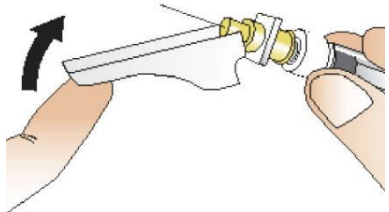
INSTRUCTIONS	RELATED IMAGE
<ul style="list-style-type: none"> With the syringe still connected to the vial adapter, gently swirl the vial, with syringe attached, until the powder is dissolved in the vial (See Figure K). Do not shake the vial. 	 <p style="text-align: center;">Figure K</p>
<ul style="list-style-type: none"> Allow the vial with the attached syringe to stand on the flat surface for 2 minutes at room temperature to allow the powder to completely dissolve (See Figure L). The plunger may rise up by itself again, this is normal. 	 <p style="text-align: center;">Figure L</p>
<p>Step 7: Draw up solution</p> <ul style="list-style-type: none"> Check the solution in the vial for particles, cloudiness, or clumps. All powder must be fully dissolved and the solution must be clear. Do not use the medicine if you see particles, cloudiness, or clumps. Use a new carton of Cablivi and call your healthcare provider if this happens. Slowly press the syringe plunger fully down. Keep the syringe on the vial and turn the whole vial, adapter and syringe- upside down. Slowly pull the plunger down to withdraw all of the solution from the vial into the syringe (See Figure M). Do not shake it. 	 <p style="text-align: center;">Figure M</p>

INSTRUCTIONS	RELATED IMAGE
<p>Step 8: Detach the syringe</p> <ul style="list-style-type: none"> After drawing up the solution into the syringe, turn the whole - vial, adapter and syringe- right-side up (with the syringe at the top) and place on the flat surface (See Figure N). 	 <p style="text-align: center;">Figure N</p>
<ul style="list-style-type: none"> Detach the filled syringe from the adapter by holding the vial and adapter in one hand and gently twisting the syringe counter-clockwise with the other hand (See Figure O). Throw away the vial and the attached adapter into a sharps disposal container. Do not touch the syringe tip or allow it to touch the clean flat surface. Place the syringe on the clean flat surface. 	 <p style="text-align: center;">Figure O</p>
<p>Step 9: Attach the needle</p> <ul style="list-style-type: none"> Open the needle package by using both thumbs to pull apart the packaging (See Figure P). Remove the needle with the needle cap from the package. 	 <p style="text-align: center;">Figure P</p>

INSTRUCTIONS	RELATED IMAGE
<ul style="list-style-type: none"> Attach the needle with the needle cap to the syringe by turning clockwise until it cannot twist any further (See Figure Q). Do not remove the needle cap. 	 <p data-bbox="1040 640 1136 667">Figure Q</p>
<ul style="list-style-type: none"> Pull back the needle safety shield (See Figure R). 	 <p data-bbox="1040 1087 1136 1115">Figure R</p>
<p>Step 10: Prepare your injection site</p> <ul style="list-style-type: none"> Select an injection site on your stomach (abdomen) (See Figure S). Avoid the 2-inch area around your belly button (navel). Select a different injection site from the one you used on the previous day to help the skin to recover after the injection. 	 <p data-bbox="1040 1472 1136 1499">Figure S</p>

INSTRUCTIONS	RELATED IMAGE
<ul style="list-style-type: none"> Clean your injection site with an alcohol swab (See Figure T). Let your skin dry. 	 <p data-bbox="1040 625 1133 653">Figure T</p>
<p>Step 11: Giving your injection</p> <ul style="list-style-type: none"> Carefully remove the needle cap from the needle and throw it away in a sharps disposal container (See Figure U). Make sure the needle does not touch anything before the injection. Hold the syringe at eye level with the needle pointing upwards. 	 <p data-bbox="1040 1050 1133 1077">Figure U</p>
<ul style="list-style-type: none"> Check to see if there are any air bubbles. If there are any air bubbles, remove them by tapping the side of the syringe with your finger until they rise towards the tip (See Figure V). 	 <p data-bbox="1040 1470 1133 1497">Figure V</p>

INSTRUCTIONS	RELATED IMAGE
<ul style="list-style-type: none"> Then, slowly push the plunger up until a small amount of liquid drips from the needle (See Figure W). 	 <p data-bbox="1036 653 1138 680">Figure W</p>
<ul style="list-style-type: none"> Gently use one hand to pinch the skin that has been cleaned between your thumb and forefinger, making a fold (See Figure X). Hold the pinch during the entire injection. 	 <p data-bbox="1040 1087 1138 1115">Figure X</p>
<ul style="list-style-type: none"> Use your other hand to insert the needle all the way into your skin fold at a 45 to 90-degree angle (See Figure Y). Push down on the plunger of the syringe until all of the solution is injected into your skin. Pull out the needle at the same angle you inserted it. Do not rub your injection site. 	 <p data-bbox="1040 1577 1138 1604">Figure Y</p>

INSTRUCTIONS	RELATED IMAGE
<p>Step 12: After your injection</p> <ul style="list-style-type: none"> • Right after your injection, move the needle safety shield over the needle until it clicks into place (See Figure Z). • In case you are bleeding at the injection site, place a cotton ball over the skin right away. Press gently on the cotton ball until the bleeding has stopped. If bleeding does not stop, call your healthcare provider. 	 <p style="text-align: center;">Figure Z</p>
<p>Step 13: Throw away (dispose of) the used syringe and vial.</p> <ul style="list-style-type: none"> • Throw away the syringe with the needle and the vial with the adapter in a sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes with your household trash. • If you do not have a sharps disposal container, you may use a household container that is: <ul style="list-style-type: none"> • made of a heavy-duty plastic, • can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out, • upright and stable during use, • leak-resistant, and • properly labeled to warn of hazardous waste inside the container. • When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. • Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container. 	