

TJET™ USER MANUAL



Tjet™

 **TEV-TROPIN®**
[somatropin (rDNA origin) for injection]

INSTRUCTIONS FOR USE

Read the following instructions before using your Tjet™ device. Be sure to read this entire manual to become familiar with your Tjet™ device and its parts before using it for your TEV-TROPIN® [somatropin (rDNA origin) for injection] injections.



Please see important information for TEV-TROPIN® enclosed in your Tjet™ Demonstration Kit.

IMPORTANT INFORMATION FOR USE

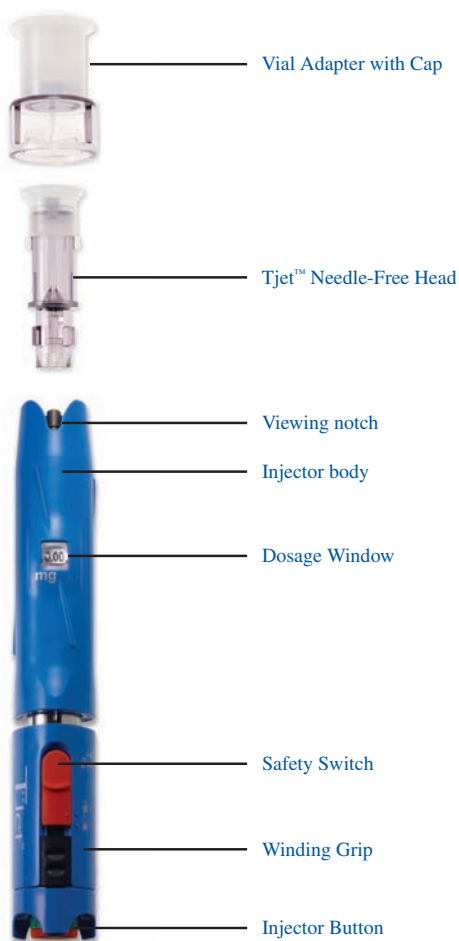
- Read the INSTRUCTIONS FOR USE before using your Tjet™ device. You or your caregiver will also receive instructions from your Growth Solutions® nurse trainer on how to use the device.
- The Tjet™ device is to be used with a vial of reconstituted TEV-TROPIN®. Reconstitute the TEV-TROPIN® as instructed by your health care provider or Growth Solutions® nurse and refer to the TEV-TROPIN® package insert for instructions for reconstitution.
- Press the Injector Button ONLY when a Needle-Free Head is attached to the Tjet™ device, the Tjet™ device has been loaded with TEV-TROPIN®, and you are intending to complete the injection.
- Never point your Tjet™ device at another person. It is spring-loaded and could cause an injury.
- Choose only the injection sites recommended by your health care provider.
- If you feel you did not get a full dose with your injection, do not inject yourself twice. Wait until your next scheduled dose.
- Use each Tjet™ Needle-Free Head for NO more than one week, and then replace with a new Needle-Free Head.
- When winding the Tjet™ device, pay attention to the solid black and red bars in the Dosing Window. These bars are indications that you are approaching the point where you should not wind the Tjet™ device any further.
- Do not store your Tjet™ device with the black bar or black dot showing in the Dosage Window. The Tjet™ Needle-Free Head may break. This could cause an injury or damage your Tjet™ device.
- It is important that you store the Tjet™ device between uses as instructed in this manual.
- Store your TEV-TROPIN® in a refrigerator at 36°F to 46°F (2°C to 8°C).
- Do not store your Tjet™ device in the refrigerator.
- Each Tjet™ device is for use by one patient only. Do not share it with other people.

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OVERVIEW OF THE TJET™ DEVICE AND ITS COMPONENTS

The following items are included with your Tjet™ device. You will need all of these items before you begin your injections of TEV-TROPIN®.



SAFE USE OF THE TJET™ DEVICE



Never use the Tjet™ Needle-Free Head for more than one week. If used more than a week, you could get the wrong dose of medicine or damage your Tjet™ device.

Never press the Injector Button of your Tjet™ device unless you are using it to give the injection.

Never point your Tjet™ device at another person. It is spring-loaded and could cause an injury.

For safe use of your Tjet™ device:

- Each Tjet™ device is for one patient only. Do not share it with other people.
- If you have any severe bleeding, bruising, pain, or any other effect caused by your Tjet™ device injection, contact your Growth Solutions® nurse right away.

For safe injections using the Tjet™ device:

- Wash your hands before using the Tjet™ device.
- Clean the rubber seal on top of the TEV-TROPIN® vial with an alcohol pad.
- Clean the injection site as instructed by your Growth Solutions® nurse.
- Get your injection ready in a clean area.
- Do not touch the Tjet™ Needle-Free Head. Keep the Tjet™ Needle-Free Head clean when getting the injection ready and when giving the injection.
- Clean the Tjet™ Needle-Free Head with an alcohol pad just before you use it for the injection and before putting it away.

PREPARING THE TJET™ DEVICE

The Tjet™ device comes in a sealed plastic bag.

If the bag is not sealed, **do not use the device**. Call your Patient Support Center at 1-866-TEV-TROP (1-866-838-8767).

Before using your Tjet™ device, make sure:

- The Injector Button is seen easily at the bottom of the Winding Grip and the green band is showing.
- The Safety Switch is in the locked position.
- The Dosage Window says “mg.”

See Figures A1 and A2.

If your Tjet™ device looks like Figure A3, you should:

1. Hold the Tjet™ device so that you can see the Dosage Window.

Note: There are two Arrows, 1 and 2, on the side of the Winding Grip.

2. Turn the Winding Grip in the direction of Arrow 1 until you hear and see the Injector Button pop out. You will see the green band on the button. See Figure B.

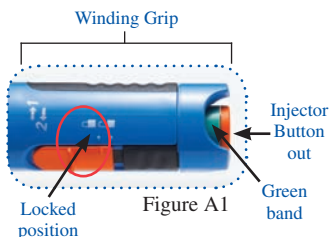


Figure A1



Figure A2



Figure A3

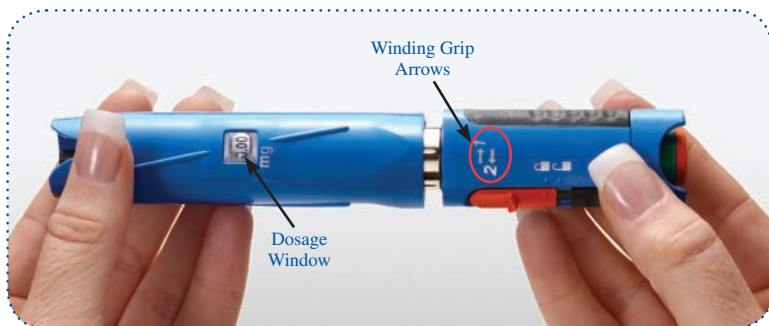


Figure B

3. Keep turning the Winding Grip in the direction of Arrow 1 until the black bar appears in the Dosage Window.
4. Do not turn the Winding Grip past the end of the solid black bar. *See Figure C.*
5. Next, turn the Winding Grip in the direction of Arrow 2 until you see 0.00 in the Dosage Window. *See Figure D.*

The Tjet™ device is now ready for you to attach the Tjet™ Needle-Free Head. *See Figure E.*



Figure C



Figure D



Figure E

ATTACHING A TJET™ NEEDLE-FREE HEAD

The Tjet™ Needle-Free Head can be used for one week before you need to change to a new Tjet™ Needle-Free Head. After one week, the Tjet™ Needle-Free Head begins to wear out and must be replaced.

The Tjet™ Needle-Free Head comes in 3 sizes: A, B, and C. Your Tjet™ Demonstration Kit contains 5 size A Heads. *See Figure F.* If you need size B or C Heads, contact your Patient Support Center at 1-866-TEV-TROP (1-866-838-8767).

For the first injection, your Growth Solutions® nurse will start with the size A Tjet™ Needle-Free Head. After your first injection, read the section of this manual called “Evaluating your injections.” Your Growth Solutions® nurse will help you decide which size Tjet™ Needle-Free Head to use.

Once you and your Growth Solutions® nurse agree that you can use the Tjet™ device the right way, use this manual to go over each step when getting ready and giving the TEV-TROPIN® injection.

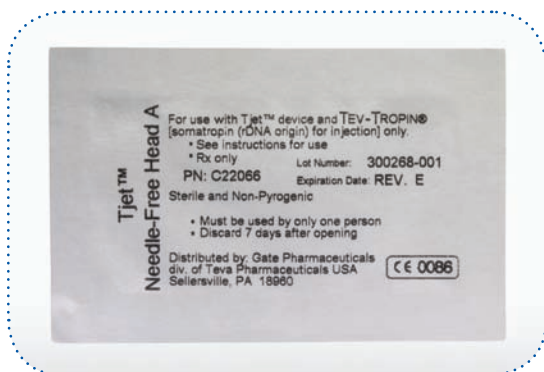


Figure F

HANDLING THE TJET™ NEEDLE-FREE HEAD

Now that you and your Growth Solutions® nurse have attached the first Tjet™ Needle-Free Head and have decided on the correct Tjet™ Needle-Free Head size, follow these instructions for attaching a new Tjet™ Needle-Free Head to the Tjet™ device:

Do not touch the tip of the Tjet™ Needle-Free Head. The part of the Tjet™ Needle-Free Head that touches your skin should be as clean as possible when injecting TEV-TROPIN®.

To attach the Tjet™ Needle-Free Head to the Tjet™ device:

- Open a new sterile Tjet™ Needle-Free Head package.
- Align the square blocks of the Tjet™ Needle-Free Head with the viewing notch of the Tjet™ device. *See Figure G1.*
- Be sure the Injector Button is out and you can easily see the green band, and 0.00 appears in the Dosage Window.
- Push the Tjet™ Needle-Free Head straight into the injector until it stops and the ring can no longer be seen. *See Figure G2.*
- While pushing down on the Tjet™ Needle-Free Head, turn it to the left until it locks into place.
- The tabs on the side of the Tjet™ Needle-Free Head must line up with the marks on the Tjet™ device. *See Figure G3.*
- Place the plastic Cap onto the Tjet™ Needle-Free Head when it is not being used.

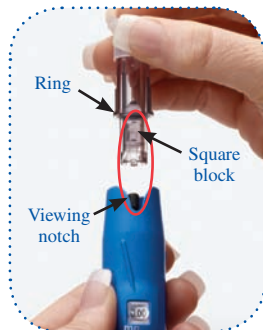


Figure G1



Figure G2

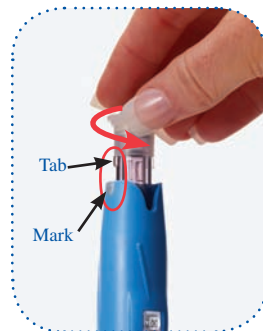


Figure G3

ATTACHING A VIAL OF TEV-TROPIN® AND VIAL ADAPTER TO YOUR TJET™ DEVICE

You will need:

- A prepared vial of TEV-TROPIN® for injection.
- A new Vial Adapter that attaches the vial to the Tjet™ Needle-Free Head.

Follow these steps to put the Vial Adapter on the TEV-TROPIN® vial:

1. First, make sure your TEV-TROPIN® vial is ready to use. Prepare (reconstitute) your TEV-TROPIN® as directed by your health care provider. For instructions on reconstituting TEV-TROPIN®, please see your TEV-TROPIN® patient information, or visit www.tevtropin.com.
2. Clean the rubber seal on top of the vial with an alcohol pad. *See Figure H.*
3. Open a new Vial Adapter package. The Vial Adapter has a pointed tip on one end. *See Figure I.*



Figure H



Figure I

4. Place the pointed tip of the Vial Adapter in the center of the rubber seal on the top of the vial.
See Figure J1.

5. Firmly push the Vial Adapter tip down into the vial, turning the Vial Adapter gently until it pushes through the rubber seal and snaps onto the vial. *See Figure J2.*

6. Remove the Cap from the Vial Adapter by holding onto the vial and Vial Adapter in one hand and pulling the Cap straight off with the other hand. Put the Cap back onto the Vial Adapter when storing.
See Figure J3.

7. Use one Vial Adapter with one vial only—do not remove the Vial Adapter from the used vial. Throw away the Vial Adapter when you throw away the vial.



Figure J1



Figure J2



Figure J3

PRIMING THE TJET™ DEVICE

You must prime your Tjet™ device with TEV-TROPIN® each time you use a new Tjet™ Needle-Free Head. Priming removes most of the air bubbles inside the Tjet™ Needle-Free Head.

- Look for air bubbles inside the Tjet™ Needle-Free Head. If you see bubbles, firmly tap the side of the Tjet™ device to move them to the tip of the Tjet™ Needle-Free Head. See *Figure K*.



Figure K

Important:

Make sure that 0.00 is showing in the Dosage Window of the Tjet™ device and that the Injector Button is popped out before you begin the following steps.

1. Remove the Vial Adapter Cap, if one is in place on the vial. To remove the Cap, grasp the Vial Adapter just under the Cap. Do not hold the glass vial when removing the Cap, as this may cause the vial to leak.
2. Remove the Protective Cap on the Tjet™ device. See *Figures L1 and L2*.
3. Make sure the tabs on the Tjet™ Needle-Free Head are lined up with the slots in the Vial Adapter. See *Figure L3*.
4. Push the Tjet™ Needle-Free Head straight down onto the Vial Adapter until it locks into place. See *Figure L4*.



Figure L1



Figure L2



Figure L3



Figure L4

5. Turn the Tjet™ device over so that the vial is above the Tjet™ Needle-Free Head. See Figure M.



Figure N



Figure M

6. With the vial above the Tjet™ Needle-Free Head, turn the Winding Grip in the direction of Arrow 2 until the number 0.15 appears in the Dosage Window. See Figure N.

7. Now, turn the Tjet™ device so that the Tjet™ Needle-Free Head is below the Tjet™ device. The vial can be placed on a table or other flat surface. See Figure O1. Hold onto the Vial Adapter and pull the Tjet™ Needle-Free Head straight off of the Vial Adapter. See Figure O2.

1. Hold vial on flat surface



Figure O1

2. Pull straight off



Figure O2



Figure P

8. Move the orange Safety Switch to the unlocked position (*see Figure P*), and point your Tjet™ device so that the Tjet™ Needle-Free Head is facing down and away from people.
9. Press the green Injector Button to empty the liquid from the Tjet™ device. *See Figure Q.*
10. Your Tjet™ device is now primed.



Figure Q

Getting the Tjet™ device ready for storage:

- Turn the Winding Grip of the Tjet™ device in the direction of Arrow 1 until you hear and see the green Injector Button pop out at the bottom. You should be able to see the green band on the Injector Button. *See Figure R.*

See Figure R.

- Keep turning the Winding Grip in the direction of Arrow 1 until the black bar appears in the Dosage Window. *See Figure S.*

See Figure S.

- Turn the Winding Grip in the direction of Arrow 2 until you see 0.00 in the Dosage Window. *See Figure T.*

See Figure T.

- Your Tjet™ device is now ready for storage or the next injection.

- If storing, put the Protective Cap on the Tjet™ Needle-Free Head.



Figure S



Figure T



Figure R

PREPARING THE TJET™ DEVICE FOR INJECTION

- Take off the Vial Adapter Cap from the TEV-TROPIN® vial.
- Make sure that 0.00 is showing in the Dosage Window and that the green Injector Button is popped out.
- Take off the Protective Cap from the Tjet™ Needle-Free Head.
- Make sure the tabs on the Tjet™ Needle-Free Head are lined up with the slots in the Vial Adapter. Push the Tjet™ Needle-Free Head straight down into the Vial Adapter until it locks into place. *See Figure U.*

Important: Do not touch the glass vial, as this may cause it to leak.

- Turn the Tjet™ device and vial so that the vial is above the Tjet™ Needle-Free Head. Hold your Tjet™ device in this position.
- Turn the Winding Grip in the direction of Arrow 2 until your prescribed dose appears in the Dosage Window. Follow your health care provider's instructions for your dose. *See Figure V.*

Note: If you turn the Winding Grip past your prescribed dose, just turn the Winding Grip back to your prescribed dose. Turn the Winding Grip in the direction of Arrow 1.



Figure U



Figure V

- Look for air bubbles inside the Tjet™ Needle-Free Head. If you see bubbles, firmly tap the side of the Tjet™ device to move them to the tip of the Tjet™ Needle-Free Head.

See Figure W.



Figure W

- Slowly turn the Winding Grip in the direction of Arrow 1 until the bubbles go into the vial.
- Fill the Tjet™ device to your prescribed dose.

See Figure X (example).



Figure X (example)

- Once you have your prescribed dose, turn the Tjet™ device so that the Tjet™ Needle-Free Head is pointing down, and place the vial on a flat surface. *See Figure Y.*

- Remove the Tjet™ Needle-Free Head by holding the Vial Adapter and pulling the Tjet™ Needle-Free Head straight up and off of the Vial Adapter. *See Figure Z.*

1. Hold vial on flat surface

2. Pull straight off



Figure Y



Figure Z

If you need another vial to get your full dose of TEV-TROPIN® into the Tjet™ device:

- Prepare the second vial as directed by your health care provider.
- Attach the second prepared vial with Vial Adapter by pushing the Tjet™ Needle-Free Head into the Vial Adapter until it clicks into place.
- While holding your Tjet™ device upright, turn the Winding Grip in the direction of Arrow 2 until your correct dose appears in the Dosage Window.
- Remove the vial and Vial Adapter from the Tjet™ device.

INJECTING WITH THE TJET™ DEVICE

Ask your Growth Solutions® nurse for help with using the Tjet™ device until you feel comfortable giving the injection.

Preparing the injection site:

Choose a clean area in your home to give the injection.

Choose a site on the body for the injection that has some fat under the skin. For example (*see Figure AA*):

- **Back of upper arm:** upper fleshy part of the arm can be used in older children.
- **Upper outer thigh:** where fat is likely to be located.
- **Stomach:** a few inches on either side of the belly button (navel), but avoid the immediate area around the navel.
- **Buttocks:** upper outer area of the buttocks on either side.

You should choose only the injection sites recommended by your health care provider.

Do not pinch the skin at the injection site.

Clean the site with an alcohol pad before giving the injection.

Before giving the injection, wipe the Tjet™ Needle-Free Head with an alcohol pad. *See Figure BB.*

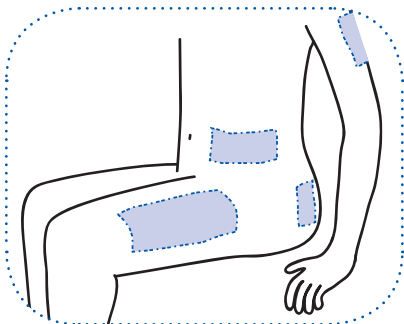


Figure AA



Figure BB

Move the orange Safety Switch to the unlocked position. See Figure CC.

The Tjet™ device is now ready for your injection.

With the Safety Switch in the unlocked position, the Tjet™ device must be handled carefully.

The patient must be in a comfortable position so that the injection site remains still during the injection.

- Sit in a chair or lie down so that the person giving the injection can see the site clearly. If it is an arm or leg, support it with a chair arm, bed, etc. The patient should be in a relaxed position. See Figure DD.
- Hold the Tjet™ device, as shown in Figure EE, gently but firmly against the skin at your injection site.
- Make sure your Tjet™ device is at a right angle to the injection site.
- The patient should relax the muscles at the injection site; press the green Injector Button.

Note: When you press this button, you will hear a noise from the Tjet™ device indicating a completed injection.

- Do not move the Tjet™ device as you press the Injector Button.
- Hold the Tjet™ device in place for 2 seconds and then remove it.

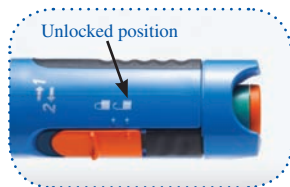


Figure CC



Figure DD



Figure EE

EVALUATING YOUR INJECTIONS

Injection evaluation guidelines

Keep track of your first few injections using the *Injection Results Log Sheet* on page 26 of this manual.

Check your skin after the injection

- It is normal to see a pinpoint of blood at the injection site, even though this is a needle-free injection.
- Your skin should be dry after the injection. A small amount of dampness on the skin is okay. If even a drop of the TEV-TROPIN® is coming out of the injection site, it means you did not get all of the TEV-TROPIN® under the skin. This can result in a lower dose than prescribed by your health care provider. If this happens, you should contact Growth Solutions® at 1-866-TEV-TROP (1-866-838-8767).
- You may feel a slight tingly sensation at the time of the injection. If you feel more pain or discomfort, call your health care provider.

The correct Tjet™ Needle-Free Head for you

If TEV-TROPIN® leaks from the injection site during 2 of your first 3 injections, contact Growth Solutions® at 1-866-TEV-TROP (1-866-838-8767). They can help to decide if you need to change to a different size Tjet™ Needle-Free Head.

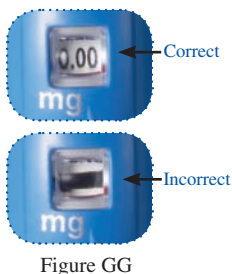
If you don't get the full dose with your injection, do not inject yourself twice. Simply wait until your next scheduled dose.



STORING THE TJET™ DEVICE BETWEEN INJECTIONS

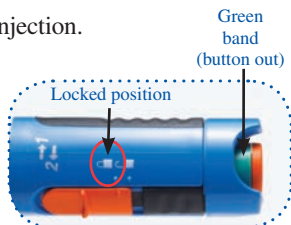
It is important to store your Tjet™ device the right way.

- After you have received the injection, turn the Winding Grip in the direction of Arrow 1 until the green Injector Button pops out. *See Figure FF.*
- Turn the Winding Grip in the direction of Arrow 2 until you see 0.00 in the Dosage Window. *See Figure FF.*



Remember: Do not store your Tjet™ device with the black bar or black dot showing in the Dosage Window. The Tjet™ Needle-Free Head may break. This could cause damage to your Tjet™ device. *See Figure GG.*

- Make sure the Safety Switch is in the locked position. *See Figure HH.*
- Wipe the Tjet™ Needle-Free Head with an alcohol pad.
- Place the Protective Cap on the Tjet™ Needle-Free Head, and place the Tjet™ device in its case.
- Your Tjet™ device can be stored until your next injection.
- Do not store your Tjet™ device in the refrigerator.
- Place the Vial Adapter Cap on the Vial Adapter and store the TEV-TROPIN® vial in your refrigerator at 36°F to 46°F (2°C to 8°C).



REMOVING A TJET™ NEEDLE-FREE HEAD

Each Tjet™ Needle-Free Head can be used for up to 1 week and then removed and thrown away. You may not get the right amount of TEV-TROPIN® if a Tjet™ Needle-Free Head is used for longer than 1 week.

To take off a Tjet™ Needle-Free Head:

1. Turn the Winding Grip in the direction of Arrow 1 until the green Injector Button pops out and you see the green band. *See Figure II.*
2. Keep turning the Winding Grip in the direction of Arrow 1 until you see the black bar in the Dosage Window.
3. Turn the Winding Grip in the direction of Arrow 2 until you see 0.00 in the Dosage Window.
4. You are now ready to take off the Tjet™ Needle-Free Head.
5. Turn the Tjet™ Needle-Free Head $\frac{1}{4}$ turn to the right, then pull the Tjet™ Needle-Free Head straight off of the Tjet™ device. *See Figure JJ.*



Figure JJ

CARE, MAINTENANCE, AND SERVICE

- **Never** discharge your Tjet™ device by pushing the green Injector Button unless a Tjet™ Needle-Free Head is attached and filled with TEV-TROPIN®.
- Never turn the Winding Grip past 2.50 in the Dosage Window.
- Clean the outside of your Tjet™ device with a damp cloth. Use clean water only.
- Do not use alcohol except to wipe the Tjet™ Needle-Free Head before your injection and before storing the Tjet™ device.
- Do not use cleaners with ammonia or phenol, glass cleaners, or any abrasive cleaners. These will damage your Tjet™ device.
- Keep your Tjet™ device and Tjet™ Needle-Free Heads away from extreme hot or cold temperatures.
- Store and use your Tjet™ device at room temperature between 59°F and 86°F (15°C to 30°C).
- Do not turn your Tjet™ Winding Grip past the red bar in the Dosage Window. *See Figure KK.*
- The life of the Tjet™ device is approximately 4 years.

Note: If you do not follow the instructions above, you could damage your Tjet™ device and void the warranty.



Figure KK

ORDERING REPLACEMENT SUPPLIES

Tjet™ supplies, including Vial Adapters and Tjet™ Needle-Free Heads, can be ordered by calling Growth Solutions® toll-free at 1-866-TEV-TROP (1-866-838-8767).

INJECTION RESULTS LOG SHEET

Date	Tjet™ Needle- Free Head (A, B, or C)	Injection Site	Dosage	Result

**Please see important information for TEV-TROPIN®
enclosed in your Tjet™ Demonstration Kit.**



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