INSTRUCTIONS FOR USE
EMPAVELI® (em-puh-vel-ee)
(pegcetacoplan)
injection, for subcutaneous use
infusion pump

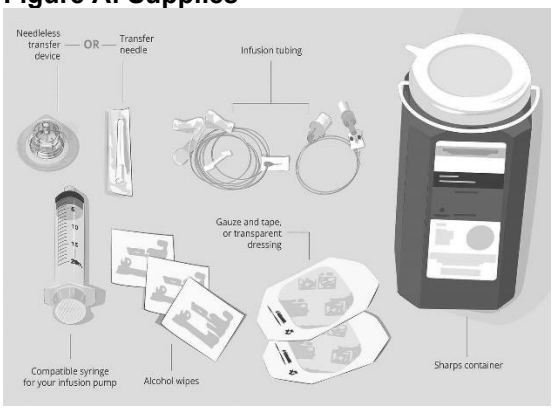
Important Information
This Instructions for Use is for the infusion pump only. If using EMPAVELI Injector, follow the Instructions for Use that comes with the EMPAVELI Injector.

Read **this** Instructions for Use before you start using EMPAVELI with an infusion pump and each time you get a refill as there may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. Your healthcare provider should show you or your caregiver how to infuse EMPAVELI the right way before you use it for the first time. Ask your healthcare provider about any instructions you do not understand.

How should I store EMPAVELI?
- Store vials of EMPAVELI in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light.
- Do not use EMPAVELI past the expiration date stamped on the carton.

Keep EMPAVELI and all medicines out of the reach of children.

<table>
<tr><td>Step 1</td><td>Prepare for infusion
Before you start:
• Find a well-lit, flat work surface area, like a table.
• Remove a single vial carton from the refrigerator. Keep the vial in the carton at room temperature 68°F to 77°F (20°C to 25°C) and allow it to warm up for about 30 minutes.
• Do not try to speed up the warming process.

Gather your supplies (See Figure A):
• Infusion pump and manufacturer’s instructions (not shown)
• Compatible syringe for your infusion pump
• Transfer needle OR
• Needleless transfer device to draw up the medicine from the vial
• Infusion set (not shown; varies according to device manufacturer’s instructions)
• Infusion tubing
• Sharps container
• Alcohol wipes
• Gauze and tape, or transparent dressing</td><td rowspan="3">Figure A: Supplies
 
</td></tr>
<tr><td></td><td>Clean your work surface well using an alcohol wipe.</td></tr>
<tr><td></td><td>Wash your hands well with soap and water. Dry your hands.</td></tr>
<tr><td>Step 2</td><td>Check the vial and liquid
• Remove the vial from the carton. Carefully look at the liquid in the vial of EMPAVELI.
o EMPAVELI is a clear, colorless to slightly yellowish liquid. Check for particles or color changes (See Figure B).
Do not use the vial and call ApellisAssist at 1-866-MY-APL-ASSIST (1-866-692-7527) if:
• The liquid looks cloudy, contains particles, or is dark yellow.
• The protective flip cap is missing or damaged.</td><td>Figure B</td></tr>
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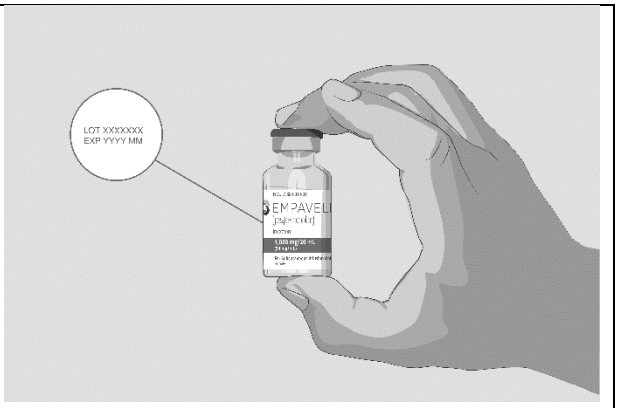
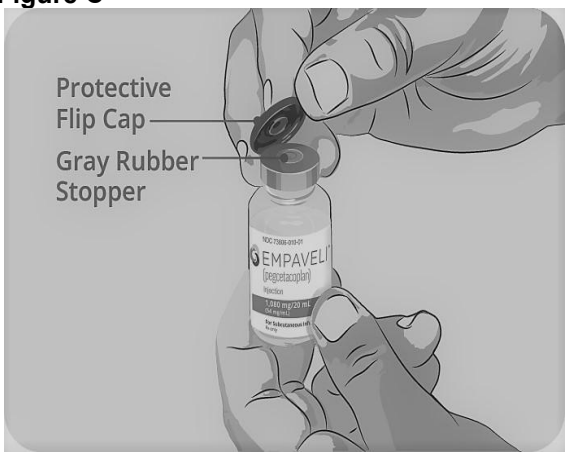
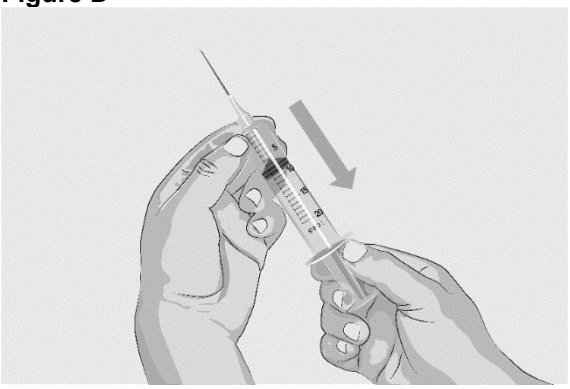
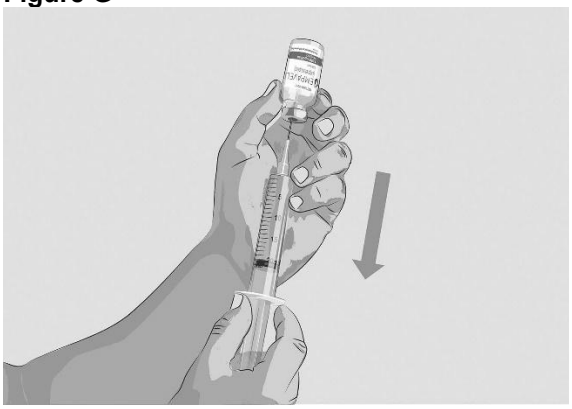
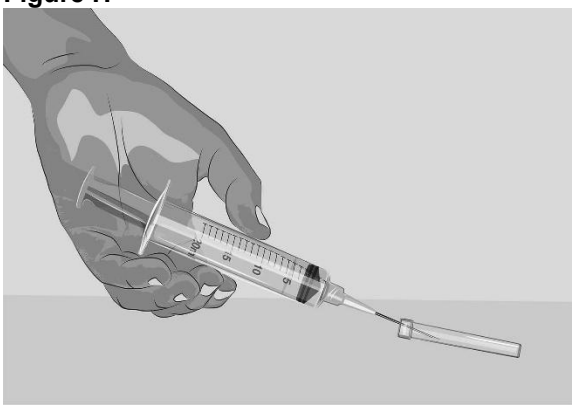
	• The expiration date on the label has passed.	
Step 3	**Prepare and fill syringe** • Remove the protective flip cap from the top of the vial to show the middle part of the gray rubber stopper of the EMPAVELI vial (See **Figure C**). Throw away the protective flip cap. • Clean the gray rubber stopper with a new alcohol wipe and allow the gray rubber stopper to dry for at least 30 seconds. **Do not** touch the exposed gray rubber stopper after wiping. **Option 1:** If using a needleless transfer device (such as a vial adapter), follow the instructions provided by the device manufacturer. OR **Option 2:** If transfer is done using a transfer needle and a syringe, follow the instructions below: • Attach a sterile transfer needle to a sterile syringe. • Pull back the plunger to the 20-mL mark to fill the syringe with air (See **Figure D**). • Push the air-filled syringe with transfer needle attached down through the center of the vial gray rubber stopper. • The tip of the transfer needle should not be in the solution to avoid creating air bubble(s) (See **Figure E**). • Gently push the air from the syringe into the vial. This will inject the air from the syringe into the vial.	**Figure C**  **Figure D**  **Figure E**

	• Turn the vial upside down and insert the transfer needle in the EMPAVELI solution (See **Figure F**).	**Figure F**
	• With the transfer needle tip in the EMPAVELI solution, slowly pull the plunger back to fill the syringe with your prescribed dose (See **Figure G**). Your first dose, second dose, and maintenance dose may be different. • Double check that you have withdrawn your prescribed dose. • Remove the filled syringe with EMPAVELI and the transfer needle from the vial. • Throw away the vial with the needleless transfer device attached and any remaining EMPAVELI solution into the household trash. • Remove the transfer needle by **using 1 hand** to slide the needle into the needle cap and **scoop upwards** to cover the needle (See **Figure H**). • After the needle is covered, push the needle cap down towards the syringe to fully attach it **with 1 hand** to prevent an accidental stick with the needle (See **Figure I**).	**Figure G**  **Figure H**  **Figure I**

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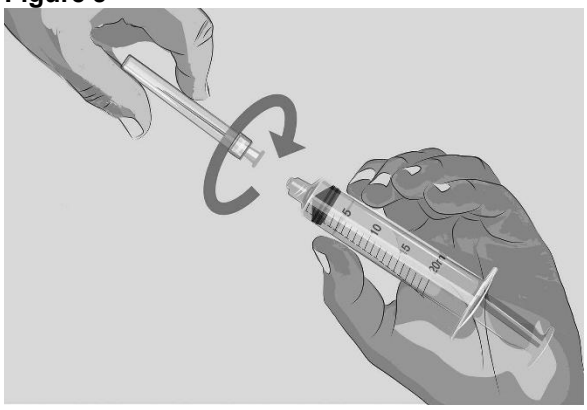
- Twist off and remove the transfer needle (See **Figure J**).

</td><td>**Figure J**
  </td></tr>
<tr><td>**Step 4**</td><td>**Prepare infusion pump and tubing**

- Gather the infusion pump supplies and follow the device manufacturer's instructions to prepare the pump and tubing.

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<tr><td>**Step 5**</td><td>**Prepare the infusion site(s)**

- Select an area on your stomach (abdomen), thighs, hips, or upper arms for the infusion(s) (See **Figure K**).

Avoid the following infusion areas:

  - Do not infuse into areas where the skin is tender, bruised, red, or hard.
  - Avoid infusing into tattoos, scars, or stretch marks.

- Use a different site(s) from the last time you infused EMPAVELI. If there are multiple infusion sites, they should be at least 3 inches apart. Change (rotate) infusion sites in between each infusion (See **Figure L**).

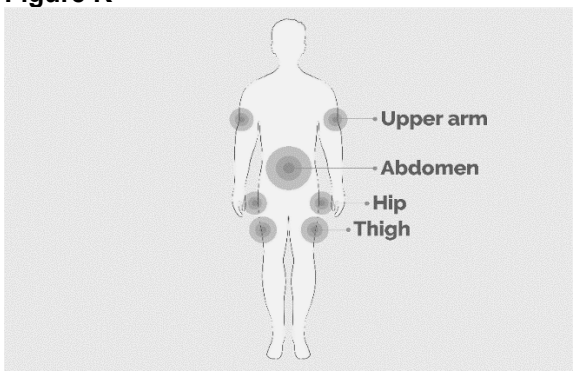
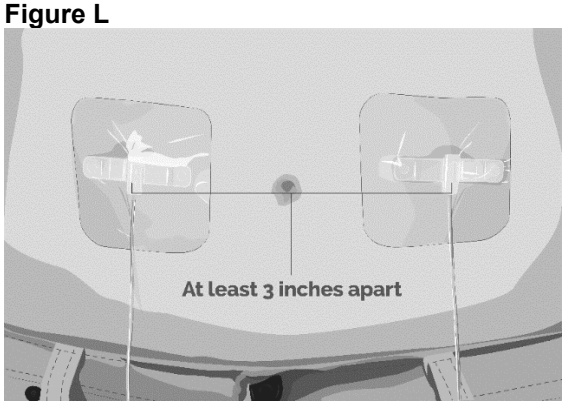
</td><td>**Figure K**
 

Figure L
 
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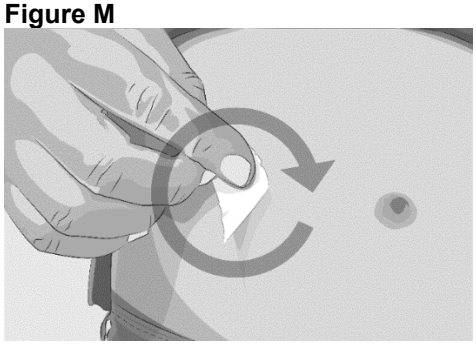
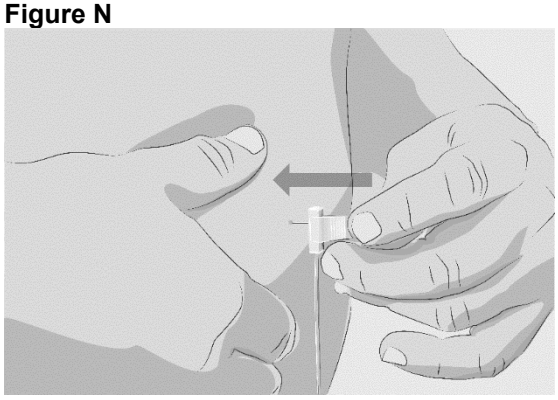
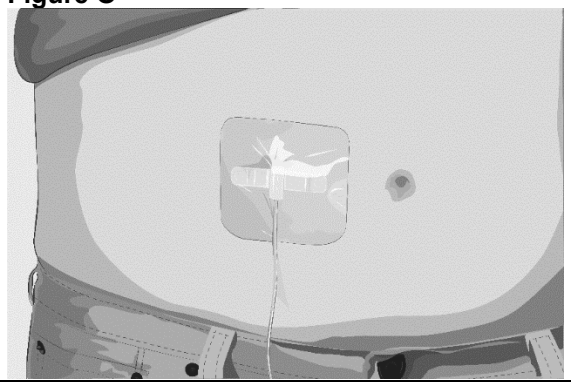
	• Clean the skin at each infusion site(s) with a new alcohol wipe, starting at the center of each infusion site and working outward in a circular motion (See **Figure M**). • Let the skin dry.	**Figure M** 
Step 6	**Insert and secure the infusion needle(s)** • Pinch the skin between your thumb and forefinger around the infusion site (where you plan to insert the needle). • Insert the needle into the skin (See **Figure N**). • Secure the needle(s) using gauze and tape or a transparent dressing placed over the infusion site(s) (See **Figure O**).	**Figure N**  **Figure O** 
Step 7	**Start infusion** • Follow the device manufacturer's instructions to start the infusion. • Start the infusion right away after drawing EMPAVELI into the syringe. • EMPAVELI infusion takes about 30 minutes (if using 2 infusion sites) or about 60 minutes (if using 1 infusion site) to complete.	
Step 8	**Complete infusion** • Follow the device manufacturer's instructions to complete the infusion.	
Step 9	**Record infusion** • Record your treatment as directed by your healthcare provider.	

<table>
<tr><td>Step 10</td><td>Clean up
After the infusion is complete, remove the dressing and slowly take out the needle(s). Cover the infusion site with a new dressing.
Remove the infusion set from the pump and throw it away into the sharps container (See Figure P).
Clean and store the infusion pump according to the device manufacturer’s instructions.</td><td></td></tr>
<tr><td>Step 11</td><td>Dispose of (throw away) used needles and syringes and EMPAVELI infusion tubing.
Put the used needles, syringes, and EMPAVELI infusion tubing in an FDA-cleared sharps disposal container right away after use (See Figure P).
Do not dispose of (throw away) the used needles, syringes, and EMPAVELI infusion tubing in your household trash.
If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
made of 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. There may be state or local laws about how you should throw away used needles and syringes.
For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA’s website at: http://www.fda.gov/safesharpsdisposal.
Do not throw away your used sharps disposal container in your household trash unless your community guidelines permit this.
Do not recycle your used sharps disposal container.</td><td>Figure P
 </td></tr>
</table>

Call 1-866-692-7527 to speak with an Apellis representative.
Manufactured for:
Apellis Pharmaceuticals, Inc. 100 Fifth Avenue Waltham, MA 02451
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