

# INSTRUCTIONS FOR USE

## EMPAVELI® Injector (pegcetacoplan)

injection, for subcutaneous use  
Single-use on-body injector

### Important Information

This Instructions for Use is for the EMPAVELI Injector only.

Read **this** Instructions for Use before you start using the Injector and each time you get a refill as there may be new information. The EMPAVELI Injector is placed on your body to give medicine under the skin. 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 inject EMPAVELI the right way before you use it for the first time. It is important that you do not try to give yourself or someone else the injection unless you have received training from your healthcare provider. Ask your healthcare provider about any instructions you do not understand.

If you have questions, concerns, or need of help, please call ApellisAssist® at 1-866-MY-APL-ASSIST (1-866-692-7527).

### SIDE 1: Filling the Syringe



#### Start here

Complete these instructions on how to prepare EMPAVELI before completing EMPAVELI Injector administration instructions on the back of this page.

#### 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, EMPAVELI Injector, and all medicines out of the reach of children.

#### Supplies needed for injection, must be obtained separately



For illustration only. The supplies you receive may look different.

#### Prepare for injection

- 1 Before you start:**
  - ▶ Find a well-lit, flat work surface area, like a table.
  - ▶ Remove a single vial carton of EMPAVELI from the refrigerator. Keep the vial in the carton at room temperature and allow it to warm up for about **30 minutes**.
  - ▶ **Do not** try to speed up the warming process.
- 2**
  - ▶ Wash your hands well with soap and water.
  - ▶ Dry your hands.

#### Check the vial and liquid

- 3**
  - ▶ Remove the vial from the carton. Carefully look at the liquid in the vial of EMPAVELI.
  - ▶ EMPAVELI is a clear, colorless to slightly yellowish liquid. Check for particles or color changes.
  - ▶ **Do not** use and call ApellisAssist if:
    - The liquid looks cloudy, contains particles, or is dark yellow.
    - The protective flip cap is missing from the top of the vial or damaged.
    - The expiration date on the label has passed.

- 4**
  - ▶ Flip up to remove the protective flip cap from the top of the vial to show the exposed middle part of the gray rubber stopper of the EMPAVELI vial.
  - ▶ Throw away the protective flip cap.

- 5**
  - ▶ Clean the gray rubber stopper on the top of the EMPAVELI vial with a new alcohol wipe.
  - ▶ Allow the gray rubber stopper to dry for at least 30 seconds.
  - ▶ **Do not** touch the exposed gray rubber stopper after wiping.

#### Prepare and fill the syringe with EMPAVELI using a needleless transfer device (such as a vial adapter)

- 6** **Always follow the Instructions for Use provided by the needleless transfer device's manufacturer (as they may differ from the following steps).**
  - ▶ **Do not** remove the needleless transfer device from the blister package.
  - ▶ **Do not** touch the spike or the inside of the needleless transfer device.
  - ▶ **Do not** use the needleless transfer device if it comes out or is dropped out of the package.
  - ▶ **Do not** use the needleless transfer device if the package is opened.

- 7**
  - ▶ Remove the cover of the needleless transfer device package.
  - ▶ Place the vial on a clean, flat surface and hold the vial by the base with one hand.
  - ▶ Using the outside of the blister package to firmly hold the needleless transfer device, push needleless transfer device straight down onto the vial top until it snaps securely into place.

- 8**
  - ▶ Remove the blister package from the needleless transfer device and throw the blister package away.
  - ▶ **Do not** touch the connector at the top of the transfer device.

- 9**
  - ▶ Remove the syringe from its packaging.
  - ▶ **Do not** touch the tip of the syringe.
  - ▶ Attach the syringe to the needleless transfer device by twisting the tip of the syringe to the right (clockwise) onto the top of the needleless transfer device.

- 10**
  - ▶ Turn the EMPAVELI vial upside down.

- 11**
  - ▶ Slowly pull the syringe plunger down to fill the syringe with EMPAVELI.

- 12**
  - ▶ Withdraw all EMPAVELI from the vial into the syringe.
  - ▶ Make sure there is 20 mL of EMPAVELI in the syringe.
  - ▶ Remove air from syringe by gently pushing on the plunger.

- 13**
  - ▶ While holding the EMPAVELI vial and syringe, turn the EMPAVELI vial and filled syringe upright and place the bottom of the EMPAVELI vial on a flat surface.

- 14**
  - ▶ Remove the filled syringe from the needleless transfer device with one hand while holding the EMPAVELI vial with the other hand and twisting the filled syringe to the left (counterclockwise).

- 15**
  - ▶ Place the syringe on a clean, flat surface while you prepare the EMPAVELI Injector. The syringe will not leak when set down.
  - ▶ **Do not** touch the tip of the filled syringe.

- 16**
  - ▶ **Do not** remove the needleless transfer device from the vial.
  - ▶ Throw away the vial with the needleless transfer device attached into the household trash.

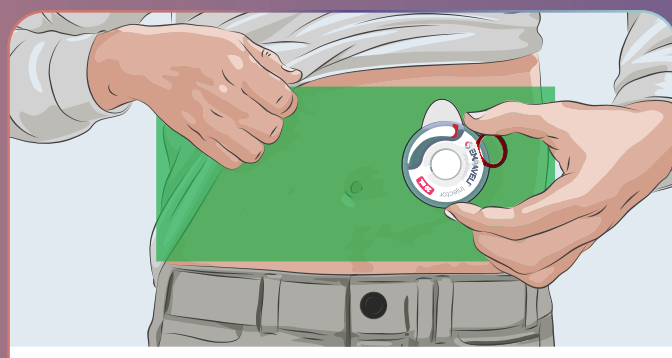
Symbol	Symbol Title	Symbol Definition
	Manufacturer	Indicates the medical device manufacturer
	Date of manufacture	Indicates the date when the medical device was manufactured
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Use by date	Indicates the date after which the medical device is not to be used
	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed
	Keep dry	Indicates a medical device that needs to be protected from moisture
	Unique device identifier	Indicates the manufacturer's device identifier so that a specific medical device can be identified
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	Do not resterilize	Indicates a medical device that is not to be resterilized
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	Prescription only	Requires prescription in the United States
<b>Manufactured for:</b> Apellis Pharmaceuticals 100 5th Avenue Waltham, MA 02451, USA		<b>Manufactured by:</b> Enable Injections, Inc. 2863 E. Sharon Road Cincinnati, OH 45241, USA
<b>Patent:</b> EnableInjections.com/patent		Copyright ©2023 Apellis Pharmaceuticals, Inc. All rights reserved. APELLIS, APELLISASSIST, EMPAVELI, and their respective logos are trademarks of Apellis Pharmaceuticals, Inc. This Instructions for Use has been approved by the U.S. Food and Drug Administration. Issued 09/2023 EMP-INJ-IFU-295EP2023-1.0
		10130600 Rev B

TURN OVER  
to continue



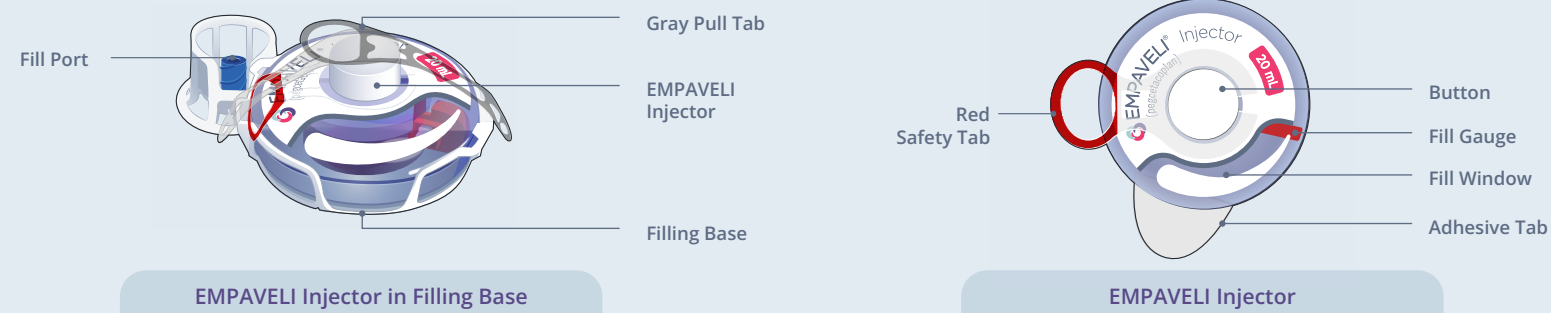
## SIDE 2: Injector Administration

Complete these instructions for administering the EMPAVELI Injector after completing syringe filling instructions on the front of this page.



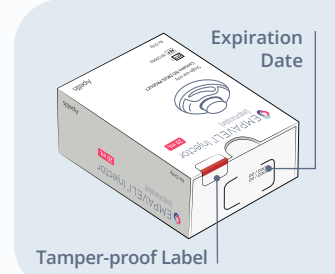
Once you complete the steps below, the end result is to attach the EMPAVELI Injector on your stomach.

### Parts of EMPAVELI Injector



### How to store the EMPAVELI Injector

- ▶ Keep the EMPAVELI Injector in unopened tray inside the original box.
- ▶ **Do not** open the tray until ready for EMPAVELI injection.
- ▶ **Store** the EMPAVELI Injector unit in clean, dry area away from heat and sunlight, at a temperature between 36°F to 86°F (2°C to 30°C).
- ▶ **Use** the EMPAVELI Injector where the temperature is between 41°F to 104°F (5°C to 40°C).



### Important Information for administration with EMPAVELI Injector

#### General use:

- ▶ **Do not** use EMPAVELI Injector if tamper-proof label has been broken.
- ▶ **Do not** use EMPAVELI Injector if you have a skin condition on your stomach (injection site).
- ▶ **Do not** use if you dropped EMPAVELI Injector.
- ▶ **Do not** use if the sealed plastic tray is open or damaged.
- ▶ **Do not** use if the expiration date on the box has passed.
- ▶ **Do not** use if you have an acrylic allergy. Tell your healthcare provider if you are allergic to acrylic.
- ▶ **Do not** reuse EMPAVELI Injector.
- ▶ **Do not** store the filled EMPAVELI Injector.
- ▶ Wear loose clothes so that they **do not** get in the way of the EMPAVELI Injector.
- ▶ **Do not** store the EMPAVELI Injector in direct sunlight. If the EMPAVELI Injector is stored in direct sunlight, **do not** use it and call ApellisAssist at 1-866-MY-APL-ASSIST (1-866-692-7527).

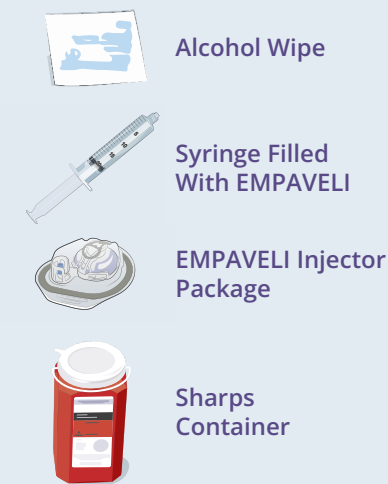
#### Using EMPAVELI Injector:

- ▶ **Do not** apply EMPAVELI Injector along the belt line or on areas where the injector will be affected by folds in the skin.
- ▶ **Do not** touch the white adhesive on the bottom of EMPAVELI Injector before attaching to stomach.
- ▶ **Do not** let your clothes touch the clean site.
- ▶ **Do not** remove the Red Safety Tab until EMPAVELI Injector is attached to body.
- ▶ **Do not** remove EMPAVELI Injector from the skin until the button pops out.
- ▶ **Do not** throw away (dispose of) the EMPAVELI Injector into household trash. See the section "Remove and Dispose of EMPAVELI Injector" for information on how to dispose of the EMPAVELI Injector.
- ▶ Choose an injection site at least 1 inch from the edge of your belly button and the edge of the EMPAVELI Injector, and 1 inch from last injection site.
- ▶ Use the EMPAVELI Injector on stomach only.

#### During injection:

- ▶ **Do not** remove EMPAVELI Injector from the skin during injection.
- ▶ **Do not** bathe, shower, exercise, use hot tubs, whirlpools, or saunas. Avoid getting your stomach wet. The EMPAVELI Injector is not waterproof. Water or sweat may loosen EMPAVELI Injector from skin.
- ▶ **Do not** sleep or bathe during injection.
- ▶ Avoid intense physical activity.
- ▶ **Do not** bump or knock the EMPAVELI Injector.
- ▶ **Do not** bump the EMPAVELI Injector Button.
- ▶ **Do not** use anything to hold the EMPAVELI Injector in place.

### Supplies needed for injection



### Questions and answers

#### Can I use more than 1 syringe to fill the EMPAVELI Injector?

No, use only 1 syringe per EMPAVELI Injector.

#### What should I do if the syringe plunger will not push down to fill the EMPAVELI Injector?

You must firmly press down on the plunger to fill the EMPAVELI Injector. It will feel like there is resistance.

#### Can I remove the EMPAVELI Injector from my stomach and put it on later to finish injection?

No. The EMPAVELI Injector cannot be reattached. If you take it off, you may not get your full dose.

#### How long should the injection take?

The injection time is approximately 30 to 60 minutes.

If the button has not popped out after 2 hours (120 minutes), press and hold the button while you remove the EMPAVELI Injector from your skin.

**⚠ Do not** touch the bottom of the EMPAVELI Injector as the needle will be exposed. Set the EMPAVELI Injector aside and call ApellisAssist at 1-866-MY-APL-ASSIST (1-866-692-7527).

#### What if the Button will not push in and lock?

Make sure that you have taken off the Red Safety Tab. If the Red Safety Tab is removed, make sure you have tried to push the Button in all the way. If you still cannot push the button all the way in, then the EMPAVELI Injector is damaged. Remove your EMPAVELI Injector and set aside. Open a new EMPAVELI Injector and start over. Call ApellisAssist at 1-866-MY-APL-ASSIST (1-866-692-7527).

#### What if the EMPAVELI Injector falls off of my body?

If the EMPAVELI Injector falls off of your body, pick it up carefully. **Do not** touch the needle or any medicine that may be on the EMPAVELI Injector. Set the EMPAVELI Injector aside and out of the reach of children. Call ApellisAssist at 1-866-MY-APL-ASSIST (1-866-692-7527) right away.

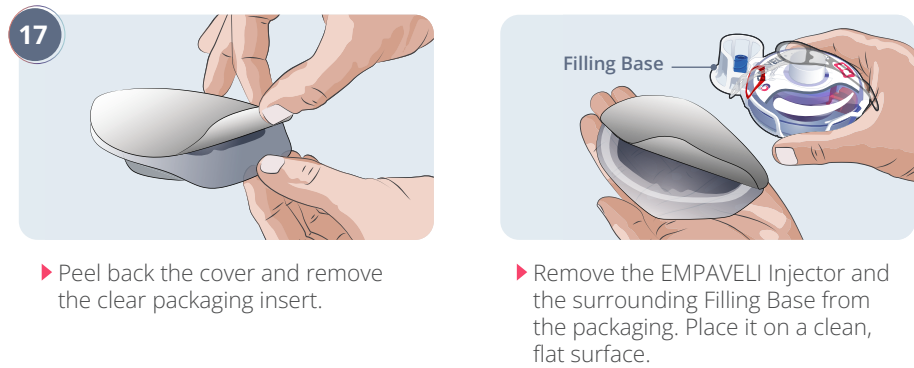
#### Is it normal for skin to be bumpy or irritated during an injection?

No. Your body may be sensitive to the adhesive on the EMPAVELI Injector or to the medicine. Call your healthcare provider right away.

#### Is it normal for skin to be red after an injection?

Your skin may be slightly red after adhesive removal. If the redness does not go away after 1-2 days, call your healthcare provider.

### Fill injector with EMPAVELI liquid



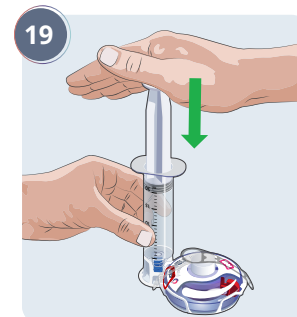
- ▶ Peel back the cover and remove the clear packaging insert.



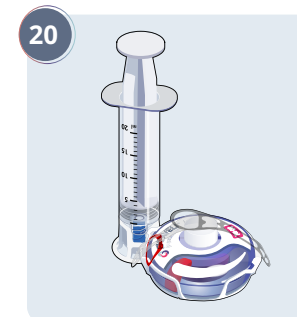
- ▶ Remove the EMPAVELI Injector and the surrounding Filling Base from the packaging. Place it on a clean, flat surface.



- ▶ Pick up the syringe filled with EMPAVELI.
- ▶ Twist the filled syringe tip to the right (clockwise) into the Fill Port until it is tight.

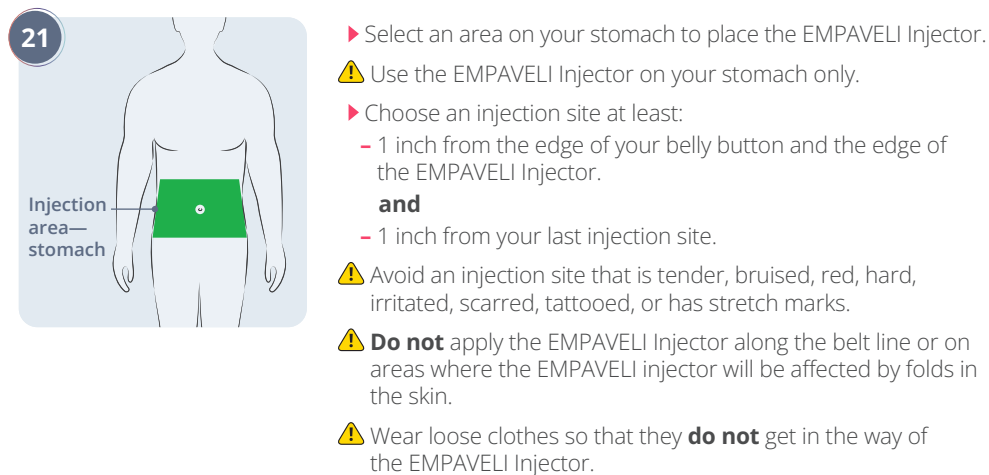


- ▶ Firmly push the syringe plunger down.
- ▶ The syringe plunger may be hard to push.
- ▶ Watch the Fill Gauge move as EMPAVELI is pushed into the injector.



- ▶ Make sure the syringe is empty. If needed, press firmly down on the syringe plunger again.
- ▶ **⚠ Do not** remove syringe from Filling Base. After the EMPAVELI Injector is filled, continue with the preparation and injection.
- ▶ **⚠ Do not** store filled EMPAVELI Injector.

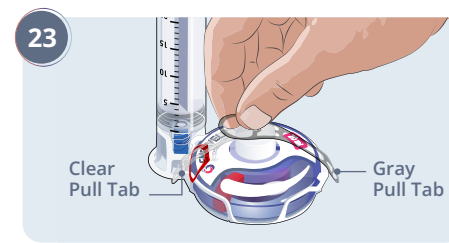
### Attach EMPAVELI Injector to stomach



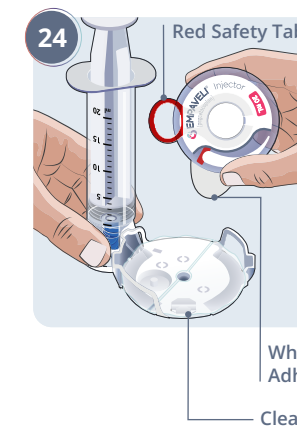
- ▶ Select an area on your stomach to place the EMPAVELI Injector.
- ▶ Use the EMPAVELI Injector on your stomach only.
- ▶ Choose an injection site at least:
  - 1 inch from the edge of your belly button and the edge of the EMPAVELI Injector.
  - and
  - 1 inch from your last injection site.
- ▶ Avoid an injection site that is tender, bruised, red, hard, irritated, scarred, tattooed, or has stretch marks.
- ▶ **Do not** apply the EMPAVELI Injector along the belt line or on areas where the EMPAVELI injector will be affected by folds in the skin.
- ▶ Wear loose clothes so that they **do not** get in the way of the EMPAVELI Injector.



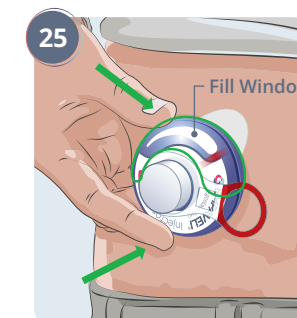
- ▶ Clean the injection site with an alcohol wipe.
- ▶ Allow the injection site to dry for at least 30 seconds.
- ▶ **⚠ Do not** let your clothes touch the clean injection site.



- ▶ Hold the Gray Pull Tab and pull. Allow both the Gray and Clear Pull Tabs to fall to the side.
- ▶ Both tabs may fall to the side or come off completely.
- ▶ **⚠ Do not** remove the Red Safety Tab until the EMPAVELI Injector is attached to body.

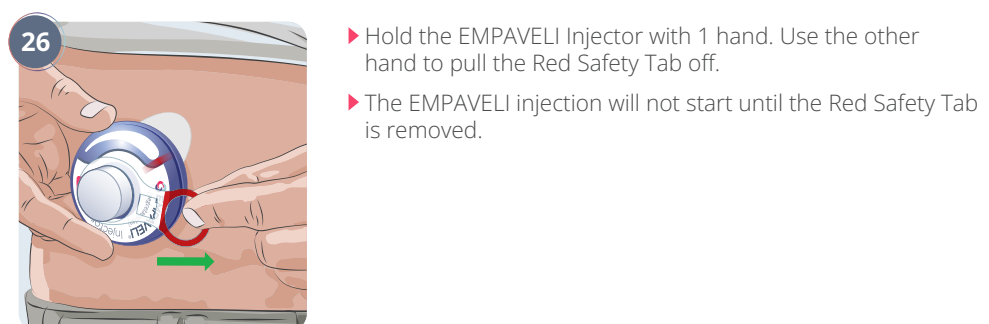


- ▶ Hold the sides of the EMPAVELI Injector and pull it straight up to remove it from the Filling Base.
- ▶ **⚠ Do not** touch the adhesive on the bottom of the EMPAVELI Injector or fold the adhesive onto itself.
- ▶ The White Adhesive will stay attached to the EMPAVELI Injector and the Clear Liner will stay attached to the Filling Base.
- ▶ **⚠ Do not** remove the Red Safety Tab until the EMPAVELI Injector is attached to your body.
- ▶ Ensure the injection site has been cleaned before attaching EMPAVELI Injector.

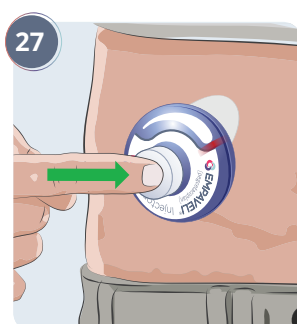


- ▶ Position the EMPAVELI Injector so that the Fill Window is pointed up toward your face.
- ▶ Press firmly on the clear portion of the EMPAVELI Injector to attach to stomach.
- ▶ **⚠ Do not** use anything to hold the EMPAVELI Injector in place.

### Start injection



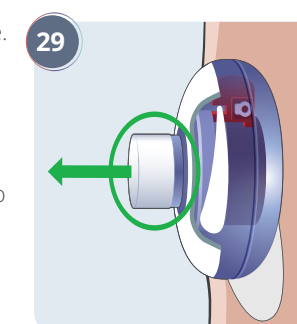
- ▶ Hold the EMPAVELI Injector with 1 hand. Use the other hand to pull the Red Safety Tab off.
- ▶ The EMPAVELI injection will not start until the Red Safety Tab is removed.



- ▶ Right away, Press the Button in firmly until it stays in place to start the EMPAVELI injection.
- ▶ Pushing the Button in will insert the needle into your skin. You may feel the needle go into your skin.
- ▶ Light daily activities can be done during the EMPAVELI injection.
- ▶ Be careful not to bump or knock the EMPAVELI Injector or button during the EMPAVELI injection.
- ▶ Keep your stomach dry. Avoid intense physical activity. **Do not** sleep or bathe during your EMPAVELI injection.

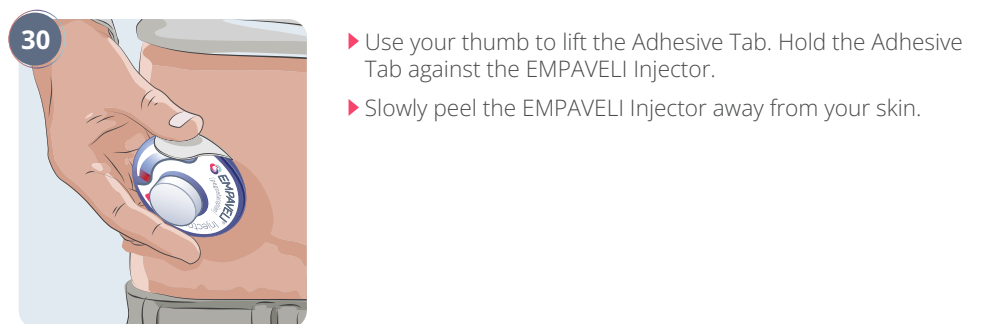


- ▶ Your EMPAVELI injection will continue as long as the button is pushed in. It may take approximately 30 to 60 minutes to complete.
- ▶ To track progress, watch the Fill Gauge move across Fill Window toward empty. It may take some time to move and may move slowly.
- ▶ **⚠ Do not** remove the EMPAVELI Injector until the button pops out.
- ▶ If the button does not pop out after 2 hours (120 minutes), refer to the Questions and Answers.
- ▶ If the EMPAVELI Injector falls off your body, refer to Questions and Answers.
- ▶ **Caution:** Holding down the button will stop the flow of medicine. Injection will begin again when the button is released.
- ▶ If you have an allergic reaction to the adhesive, call your healthcare provider right away.



- ▶ When the button pops out, the EMPAVELI injection is done. The needle will be pulled out of the skin and back into the EMPAVELI Injector.
- ▶ The button popping out is the only way to know if the EMPAVELI injection is complete. **Do not** remove the EMPAVELI Injector until the Button pops out.

### Remove and dispose of EMPAVELI Injector



- ▶ Use your thumb to lift the Adhesive Tab. Hold the Adhesive Tab against the EMPAVELI Injector.
- ▶ Slowly peel the EMPAVELI Injector away from your skin.



- ▶ Put your used EMPAVELI Injector in an FDA-cleared sharps disposal container right away after use.
- ▶ **⚠ Do not** throw away the EMPAVELI Injector in the household trash.
- ▶ The Filling Base with the syringe attached, alcohol wipe, and packaging may be placed 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 (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.
- ▶ Keep the used EMPAVELI Injector and sharps disposal container out of the reach of children.