INSTRUCTIONS FOR USE - DO NOT DISCARD **EN**

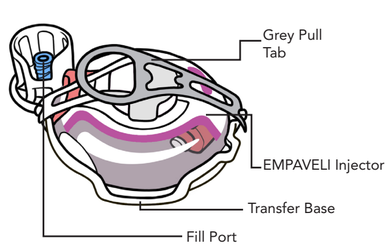
EMPAVELI® Injector
(pegcetacoplan)

For abdominal subcutaneous delivery of EMPAVELI®
Single-use On-Body Delivery System

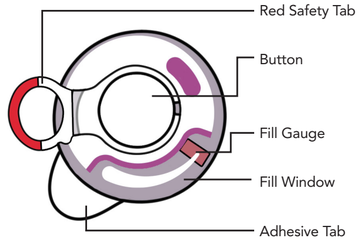
Read these Instructions for Use before you start using the EMPAVELI Injector and each time you get a new EMPAVELI Injector as there may be new information. Keep these Instructions for Use after your first dose, as you may need them for future doses. The EMPAVELI Injector is placed on your body to give medicine under the skin. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. The patient or caregiver will be instructed by a qualified healthcare professional in the use of the EMPAVELI Injector in accordance with the EMPAVELI Package Leaflet. The decision of a possibility of self-administration and home infusions should be made after evaluation and recommendation from the treating physician. Ask your healthcare provider about any instructions you do not understand.

The Intended Purpose – The EMPAVELI® Injector is intended for abdominal subcutaneous delivery of EMPAVELI.
Indications for Use – The EMPAVELI® Injector is intended for abdominal subcutaneous administration of EMPAVELI in adolescent (age 12-17) and adult patients.
Patient Target Group(s) – Adolescents (age 12-17 and ≥ 30 kg) and Adults (age 18+) in accordance with the EMPAVELI product requirements.
Intended Users – Healthcare Providers (HCPs), Caregivers, and Patients (age 12+).

Parts of EMPAVELI® Injector



EMPAVELI Injector in Syringe Transfer Base



EMPAVELI Injector

Product Description:

The EMPAVELI Injector is a sterile, non-pyrogenic, user-filled, single-use, fixed-dose subcutaneous dose delivery system. The EMPAVELI Injection System consists of the EMPAVELI Injector and Syringe Transfer Base. The EMPAVELI Injector utilizes an elastomeric balloon to deliver the EMPAVELI medicinal product, and contains an integrated needle that is inserted into the subcutaneous space once the Button is depressed. The EMPAVELI Injector design is "constant pressure" rather than a pre-set constant flow rate; target in vitro flow rates are achieved by customized needle sizes. An adhesive backing on the EMPAVELI Injector, exposed upon removal of the EMPAVELI Injector from the Transfer Base, allows for direct attachment to the skin during subcutaneous administration. The Transfer Base is intended for one (1) single-use syringe insertion and transfer of EMPAVELI upon attachment of a pre-filled, pre-measured syringe with a luer fitting (compatible with ISO 80369-7 compliant syringes). The EMPAVELI Injector is fully mechanical and does not contain any electronics or software.

Clinical Benefit:

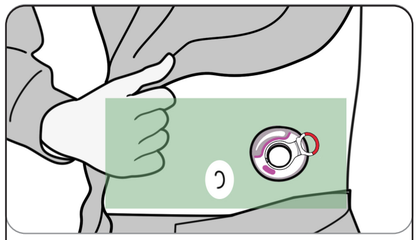
A large volume, hands-free dose administration of EMPAVELI (pegcetacoplan) to the abdominal subcutaneous space which improves patient management by reducing the burden on the user.

Warnings:

- **Warning!** Keep away from children 3 years and younger. Contains small parts.
- **Do not** use the EMPAVELI Injector if tamper-proof label has been broken.
- **Do not** use if you dropped the EMPAVELI Injector or if it appears damaged.
- **Do not** use if sealed plastic tray is open or damaged.
- **Do not** use if expiration date on the box has passed.
- **Do not** reuse the EMPAVELI Injector.
- **Do not** store filled EMPAVELI Injector
- **Do not** touch the white adhesive on bottom of the EMPAVELI Injector before attaching to abdomen.
- **Do not** let clothes touch the clean site.
- **Do not** remove the EMPAVELI Injector from skin until Button pops out.
- **Do not** throw away (dispose of) the EMPAVELI Injector into trash.
- **Do not** remove EMPAVELI Injector from skin during dose delivery.
- **Do not** use materials to hold EMPAVELI Injector in place that could compress the EMPAVELI Injector against skin.
- **Do not** put any objects in the fill port other than the filled syringe.

Precautions:

- **Do not** use the EMPAVELI Injector if patient has a skin condition on their abdomen (delivery site).
- Ensure the patient is wearing loose clothes so that they do not get in the way of the EMPAVELI Injector.
- **Do not** store the EMPAVELI Injector outside of storage conditions.
- **Do not** use the EMPAVELI Injector outside of use conditions.
- **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.
- **Do not** remove Red Safety Tab until EMPAVELI Injector is attached to body.
- Choose dose delivery site at least 2.5 cm from the edge of patient's belly button and the edge of the EMPAVELI Injector and 2.5 cm from last dose delivery site. Use the EMPAVELI Injector on abdomen only.
- **Do not** bathe, shower, exercise, use hot tubs, whirlpools, or saunas. Avoid getting abdomen wet. The EMPAVELI Injector is not waterproof. Water or sweat may loosen EMPAVELI Injector from skin.
- **Do not** sleep during dose delivery.
- Avoid engaging in intense physical activity.
- **Do not** bump or knock EMPAVELI Injector.
- **Do not** bump the EMPAVELI Injector Button.



Once you complete steps 1-9, the **result** is to attach the EMPAVELI Injector to the abdomen.

Supplies required for Dose Delivery


Alcohol wipe


Syringe filled with EMPAVELI (pegcetacoplan)*

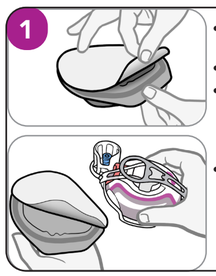

EMPAVELI Injector in packaging


Sharps Container

*Refer to the EMPAVELI Package Leaflet for the instructions to prepare and fill syringe. The EMPAVELI Injector will administer the transferred volume. The volume cannot be changed once filled.

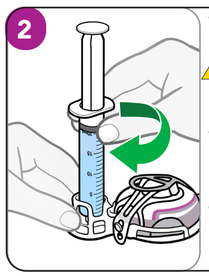
Fill the Injector with EMPAVELI Liquid

1



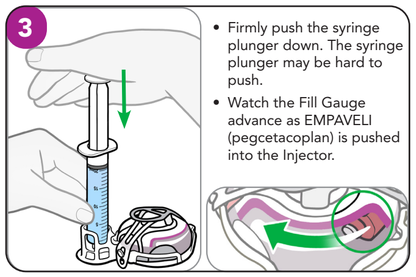
- Wash your hands well with soap and water.
- Dry your hands.
- Peel back the cover and remove the clear packaging insert.
- Remove the EMPAVELI Injector and the surrounding Transfer Base from the packaging. Place it on a clean, flat surface.

2



- Pick up the syringe filled with EMPAVELI (pegcetacoplan).
- ⚠ Double check that you have withdrawn your prescribed dose.
- The filled syringe may have a luer cap; if so, twist to the left (counter-clockwise) to remove the cap.
- **Twist** the filled syringe tip to the right (clockwise) into the Fill Port until it is tight.

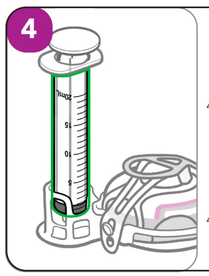
3



- Firmly push the syringe plunger down. The syringe plunger may be hard to push.
- Watch the Fill Gauge advance as EMPAVELI (pegcetacoplan) is pushed into the Injector.

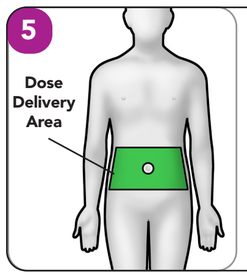
Identify and Clean the Delivery Site

4



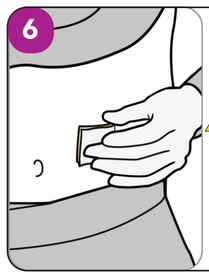
- Make sure the syringe is empty. If needed, press firmly down on the syringe plunger again.
- ⚠ **Do not** remove empty syringe from Transfer Base.
- After the EMPAVELI Injector is filled, continue with the preparation and dose delivery.
- ⚠ **Do not** store filled EMPAVELI Injector.

5



- Determine where to place the EMPAVELI Injector on the bare abdomen.
- ⚠ Use the EMPAVELI Injector on abdomen only.
- Choose a site:
  - At least 2.5 cm from the edge of patient's belly button and the edge of the EMPAVELI Injector.
  AND
  - At least 2.5 cm from the last site.
- ⚠ Avoid 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.
- ⚠ Ensure the patient is wearing loose clothes so that they do not get in the way of the EMPAVELI Injector.

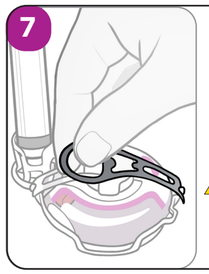
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- Clean site with an alcohol wipe.
- Allow the site to dry for at least 30 seconds.
- ⚠ **Do not** touch, fan, blow, or let clothes touch the clean site.

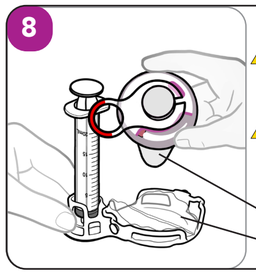
Remove the EMPAVELI Injector from Transfer Base and Attach to Abdomen

7



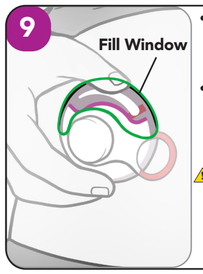
- Grasp the Grey Pull Tab and pull. Allow both the Grey and Clear Pull Tabs to fall to the side.
- The tabs may fall to the side or come off completely.
- ⚠ **Do not** remove the Red Safety Tab until the EMPAVELI Injector is attached to body.

8



- Hold the sides of the EMPAVELI Injector and pull it straight up to remove it from the Transfer 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 Transfer Base.
- ⚠ Ensure site has been cleaned before attaching the EMPAVELI Injector.

9



- Position the EMPAVELI Injector so the Fill Window is pointed up towards the patient's face.
- Press firmly on the clear portion of the EMPAVELI Injector to attach to abdomen.
- ⚠ **Do not** reposition EMPAVELI Injector once attached to the belly. EMPAVELI Injector functions regardless of Fill Window orientation.

Symbol	Symbol Title	Symbol Definition
	Manufacturer	Indicates the medical device manufacturer
USA	Country and Date of Manufacture	Indicates the country where the medical device was manufactured and the date of manufacture
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
LOT	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
UDI	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
STERILIZE	Do not resterilize	Indicates a medical device that is not to be resterilized
STERILE R	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
QTY	Quantity	Quantity of devices contained inside the commercial packaging
	Open here	Indicates the location where the package can be opened

Patent:
EnableInjections.com/patent

IFU:
EnableInjections.com/ifu

Australian Sponsor/Promoteur Australien:
Emergo Australia
Level 20 Tower II
Darling Park
201 Sussex Street
Sydney, NSW 2000
Australia

Enable Injections, Inc.
2863 E. Sharon Road
Cincinnati, OH 45241,
USA

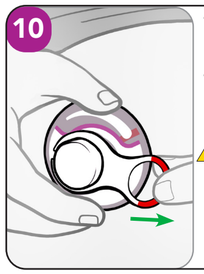
10132246 Rev. B Issued Sep2026

EMPAVELI® Injector
(pegcetacoplan)

TURN PAGE to continue.

Start Dose Delivery

10



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

⚠ **Do not** use materials to hold the EMPAVELI Injector in place that could compress the EMPAVELI Injector against the patient's skin.

11



⚠ Pushing the button will insert the needle into the patient's skin. The patient may feel the needle go into the skin.

- After placing the EMPAVELI Injector on abdomen, immediately press the button firmly until it stays in place to start the dose delivery.

⚠ Be careful not to bump, knock, or twist the EMPAVELI Injector or Button during dose delivery.

⚠ **Do not** sleep or bathe during dose delivery. During dose delivery keep abdomen totally dry. Avoid intense physical activity.

- Light daily activities can be done during dose delivery.

Track Dose Delivery

12



- Dose delivery will continue as long as Button is in. It may take about 30 to 60 minutes to complete.
- To track progress, watch the Fill Gauge move across Fill Window towards empty. Gauge is an estimate of progress. It may take some time to move and may advance slowly.

⚠ If dose delivery exceeds 2 hours (120 minutes) refer to Questions and Answers.

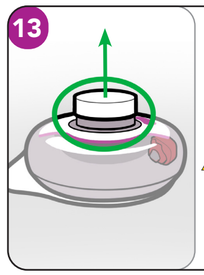
⚠ **Do not** remove the EMPAVELI Injector until the Button pops out.

⚠ **Caution:** Holding down the Button will pause the flow of medicine. Dose delivery will begin again when the Button is released.

⚠ If the patient has an allergic reaction to the adhesive, provide or seek immediate medical care.

Remove Empty EMPAVELI Injector

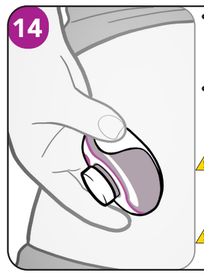
13



- When the button pops out, the dose delivery is complete, and the needle is pulled out of the skin—back into the EMPAVELI Injector—so it will not stick you or the patient.

⚠ **Do not** remove the EMPAVELI Injector until the Button pops out. The Button popping out is the only way to know if the dose delivery is complete.

14



- Use thumb to lift Adhesive Tab. Hold the Adhesive Tab against the EMPAVELI Injector.
- Slowly peel the EMPAVELI Injector away from patient's skin.

⚠ **Do not** reuse EMPAVELI Injector. Refer to Questions and Answers for more information.

⚠ **Do not** rub injection site.

Dispose of Empty EMPAVELI Injector and Supplies

15



- Put used EMPAVELI Injector in a sharps disposal or puncture-resistant container or dispose according to local regulations right away after use.
- The Transfer Base with empty syringe attached, alcohol wipe, and packaging may be disposed of according to local requirements.
- Keep these Instructions for Use after your first dose, as you may need them for future doses.
- Refer to organizational or local disposal policies to ensure compliance.

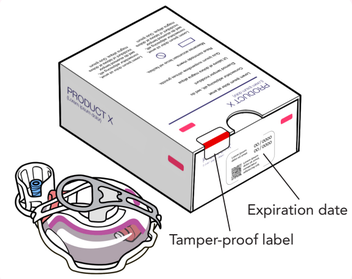
If you do not have a sharps disposal container, you may use a household container that is:

- 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 community guidelines for the right way to dispose of sharps disposal container.

- Do not dispose of full sharps disposal containers in the trash unless community guidelines permit this.
- Do not recycle full sharps disposal containers.
- Keep the used EMPAVELI Injector and sharps disposal container away from children.

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 the dose delivery.
- **Store** the EMPAVELI Injector in clean, dry area away from heat and sunlight, at temperature 2°C - 30°C (36°F - 86°F).
- **Use** the EMPAVELI Injector where the temperature is 5°C - 40°C (41°F - 104°F).



General Information

- The EMPAVELI Injector is for abdominal subcutaneous delivery of pegcetacoplan only.
- EMPAVELI Injector has a fill capacity of 20 mL.
- Consult pharmacy label for fill volume and drug delivery duration.

Questions and Answers

Can I use more than 1 syringe to fill the EMPAVELI Injector?
No, use only 1 syringe per EMPAVELI Injector.

Can I remove the EMPAVELI Injector from the abdomen and put it on later to finish dose delivery?
No. The EMPAVELI Injector cannot be reattached. If removed, the full dosage may not be delivered.

What should I do if dose delivery takes longer than 2 hours?
Press and hold the button while removing the EMPAVELI Injector from patient's skin. Put the EMPAVELI Injector aside. Consult the prescribing medical doctor.
⚠ **Do not** touch the bottom of the EMPAVELI Injector as the needle will be exposed.

What if I try to re-use the EMPAVELI Injector?
The EMPAVELI Injector has been designed to lock out after delivery of the dose and cannot be re-used. The EMPAVELI Injector cannot be re-sterilized.

Possible Complications

What if the Button won't push in and lock?
Make sure that you have taken off the Red Safety Tab. If the Safety Tab is removed, make sure you have tried to push the Button all the way in. If you still cannot push the Button all the way in, then the EMPAVELI Injector is damaged. Remove the EMPAVELI Injector and set aside. Open a new EMPAVELI Injector and start over.

What should I do if 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.

What if the EMPAVELI Injector falls off?
If the EMPAVELI Injector falls off the body, pick it up carefully. Do not touch the needle or any medicinal product that may be on the EMPAVELI Injector. Put the EMPAVELI Injector aside. Consult the prescribing medical doctor.

Other Potential Risks

- Local injection site reactions such as local tissue inflammation, irritation, swelling, or trauma
- Minor bruising, contusion, minor puncture injury, or laceration
- Systemic infection due to exposure to blood borne pathogens

Serious incidents regarding the device should be reported to the manufacturer and the competent authority of the Country or Region in which the user and/or patient is established.

It is normal to see a little bleeding. You may press a cotton ball or gauze on the injection site and cover it with a small bandage.

Contraindications

- Not intended to be used with lifesaving acute medications.
- Not intended to be used with products that need a carefully controlled flow rate.
- Not intended to be used on pregnant women.
- Not intended to be used with medicinal products that may cause permanent or severe harm requiring medical intervention if it comes into contact with the skin.
- Not intended for the delivery of blood, blood products, insulin, total parenteral nutrition, and lipid emulsions.
- Not intended for patients that have an acrylic allergy.