



# **AN INTRODUCTION TO EMPAVELI<sup>®</sup> (pegcetacoplan)**

## **Guide for patients and caregivers**

NP-20036

▼ This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA



**EMPAVELI<sup>®</sup>**  
(pegcetacoplan)

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# Contents

What is EMPAVELI? .....	3
<b>Safety considerations</b> .....	<b>3</b>
Risk of infections .....	3
Vaccinations or antibiotic therapy .....	4
<b>Set up for self-administration</b> .....	<b>5</b>
Set up for infusion .....	5
Prepare and fill syringe .....	6
Prepare infusion pump and tubing .....	8
Give the infusion .....	8
Clean up .....	10
<b>Reporting side effects</b> .....	<b>11</b>
<b>More information</b> .....	<b>11</b>

## What is EMPAVELI?

EMPAVELI is a medicine that contains the active substance pegcetacoplan. Pegcetacoplan prevents your body's immune system from destroying your red blood cells.

EMPAVELI is a medicine that is used to treat adult patients with a disease called paroxysmal nocturnal haemoglobinuria (PNH). For Subcutaneous infusion only.

## Safety considerations

### Risk of serious infections

The use of this medicine increases your risk of infections, including those caused by the bacteria *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae*. Bacterial infections may become life-threatening if not recognised and treated early.

Call your doctor or get emergency care right away if you have any of these signs and symptoms of an infection:

- Headache and a fever
- Fever and a rash
- Fever with or without shivers or chills
- Shortness of breath
- High heart rate
- Clammy skin
- Headache with a stiff neck or stiff back
- Headache with nausea (feeling sick) or vomiting
- Eyes sensitive to light
- Muscle aches with flu-like symptoms
- Confusion
- Extreme pain or discomfort

### Vaccinations or antibiotic therapy

- ▶ Vaccines against bacteria lower the risk of getting infections. However, vaccines do not prevent all infections.
- ▶ Your doctor will ensure that you receive vaccination against several types of bacteria if you have not had these vaccines in the past.
- ▶ If you have had these vaccines in the past, you might still need additional vaccinations before starting treatment with EMPAVELI.
- ▶ These vaccinations should be given at least 2 weeks before beginning EMPAVELI therapy.
- ▶ If you cannot be vaccinated 2 weeks before beginning EMPAVELI therapy, your doctor will prescribe antibiotics (medications to treat bacterial infections) to reduce the risk of infection, for 2 weeks after you have been vaccinated.
- ▶ When you have been vaccinated your doctor will be given a controlled distribution reference number. Your doctor should write this number onto your Patient Alert Card. You will need to show this number to your pharmacist who needs before they can dispense EMPAVELI.

### Patient Card:

- ▶ You will receive a Patient Card from your doctor.
- ▶ This card will have your unique controlled distribution reference number (CD reference number)
- ▶ Carry this card at all times during treatment and for 8 weeks after your last dose.
- ▶ Show this card to any healthcare provider who treats you. This will help them diagnose and treat you correctly.
- ▶ Show this card to the pharmacy when picking up your prescription
- ▶ Get treatment right away for any symptoms of bacterial infection even if you do not have your card on you.

### Set up for self-administration

EMPAVELI is given as a subcutaneous (under the skin) infusion with an infusion pump. Your doctor will take care of your infusions at the beginning. After you get proper training in subcutaneous infusion by your doctor.

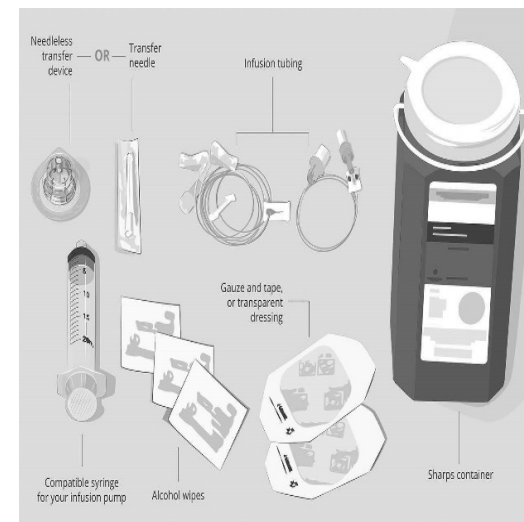
### Set up for infusion

Find a well-lit, flat and clean area where you have enough space to have all the equipment you need within reach.

### Gather your supplies:

- ▶ Syringe system infusion
- ▶ pump and manufacturer's instructions (not shown)
- ▶ Compatible syringe
- ▶ Transfer needle OR
- ▶ Needleless transfer device to draw up product from the vial
- ▶ Infusion set (not shown; varies according to device manufacturer's instructions)
- ▶ Infusion tubing and Y-connector (if required)
- ▶ Sharps container
- ▶ Alcohol wipes
- ▶ Gauze and tape, or transparent dressing

### Gather your supplies:



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

### Let the solution warm up.

- ▶ Take one single 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 using a microwave or any other heat source.
- ▶ Clean your work area well using an alcohol wipe (disinfectant in a disposable cloth).
- ▶ Wash your hands thoroughly with soap and water and dry your hands.

### Inspect the vial and liquid.

- ▶ Take the vial from the carton. Carefully look at the liquid in the vial (see picture on the right). EMPAVELI is a clear, colourless or slightly yellowish liquid. Check for no particles or colour changes.

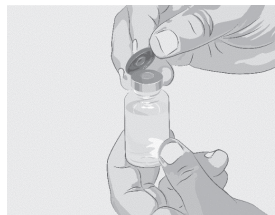


#### Do not use the vial if:

- ▶ The liquid looks cloudy, contains particles, or is dark yellow.
- ▶ The protective flip cap is missing or damaged.
- ▶ The expiration date (EXP) on the label has passed.

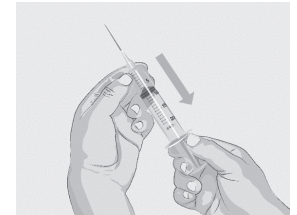
### Prepare and fill syringe

- ▶ Remove the protective flip cap from the vial to show the middle part of the grey rubber stopper of the vial (see picture on the left). Throw the cap away. Clean the stopper with a new alcohol wipe and allow the stopper to dry.



### You have two options to transfer the liquid from the vial to the transfusion pump:

**Option 1:** If you use a needleless transfer device (such as a vial adapter), follow the instructions provided by the device manufacturer.



**Option 2:** If using a transfer needle and syringe, follow the instructions below.

1. Attach a sterile transfer needle to a sterile syringe.
2. Pull back the plunger to the 20 mL mark to fill the syringe with air (see picture on the right).

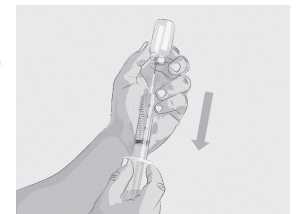
3. The vial in an upright position (NOT upside down), push the air-filled syringe with transfer needle attached through the centre of the vial stopper. The tip of the transfer needle should not be in the liquid to avoid creating bubbles (see picture on the right). Gently push the air from the syringe into the vial.



4. Turn the vial upside down (see picture on the right).



5. With the needle tip in the liquid, slowly pull the plunger to fill the syringe with all the liquid (see picture on the right).



6. Remove the filled syringe and the transfer needle from the vial.
7. Remove the transfer needle by using one hand to slide the needle into the needle cap and scoop upwards to cover the needle.

- ▶ Once the needle is covered, push the needle cap towards the syringe to fully attach it with one hand to prevent an accidental stick with the needle.
- ▶ Twist off and remove the transfer needle

### Prepare infusion pump and tubing

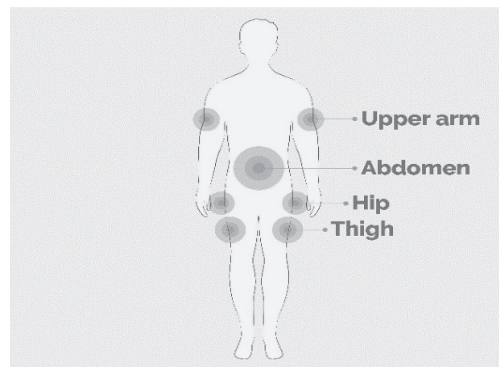
Gather the infusion pump supplies and follow the device manufacturer’s instructions to prepare the pump and tubing.

### Give the infusion

#### Choose infusion site(s).

The best places to use for the infusion are:

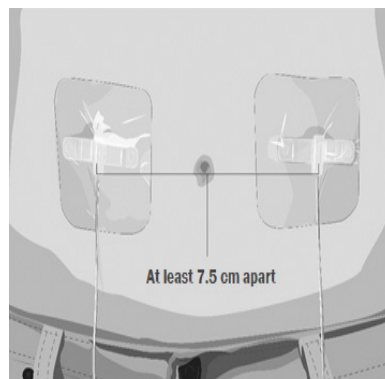
- ▶ The abdomen (except for the five centimetres area around the belly button).
- ▶ The top of the thighs.
- ▶ The upper outer areas of the buttocks/hips\*.
- ▶ The outer area of the upper arms\*.



\* Only really suitable if someone else is giving you the infusion.

#### Change the place of the infusion each time so one area does not become sore.

If there are multiple infusion sites, they should be at least 7.5 cm apart (see picture on the right). Rotate infusion sites in between each infusion.

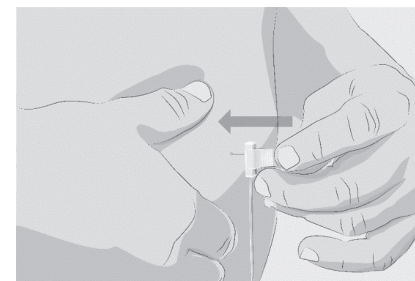
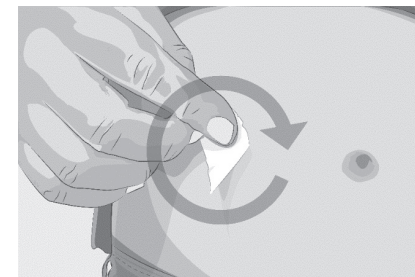


#### Avoid the following infusion areas:

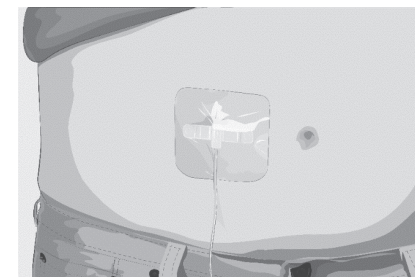
- ▶ Do not infuse into skin that is tender, bruised, infected, or hard.
- ▶ Avoid infusing into tattoos, scars, or stretch marks.

### Start the infusion right away after drawing EMPAVELI into the syringe.

1. Clean the skin at each infusion site(s) with a new alcohol wipe, starting at the centre and working outward in a circular motion (see picture on the right).
2. Let the skin dry off naturally in the air for a few seconds.
3. Pinch the skin between your thumb and forefinger around the infusion site (where you plan to insert the needle).
4. Insert the needle into the skin as shown by your nurse or doctor (see picture on the right). Follow the device manufacturer’s instructions on the angle of the needle.



5. Secure the needle(s) using sterile gauze and tape or a transparent dressing placed over the infusion site(s) (see picture on the right).



6. Follow the device manufacturer’s instructions to start the infusion. EMPAVELI infusion takes about 30 minutes (if using 2 infusion sites) or about 60 minutes (if using 1 infusion site) to complete.
7. Follow the device manufacturer’s instructions to complete the infusion and record your treatment as directed by your doctor.

## 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.
- ▶ Disconnect the infusion set from the pump.
- ▶ Put the used needles, syringes, and infusion tubing into the sharps disposal container right away after use. Do not recycle a used sharps disposal container.

Do not throw away the used needles, syringes, and infusion tubing in your household trash

Keep used needles, syringes, and other equipment out of reach and sight of children

- ▶ Throw away all used disposable supplies and the empty vial as recommended by your doctor.
- ▶ Clean and store the infusion pump according to the device manufacturer's instructions.

Refer to the EMPAVELI Patient Information Leaflet and the infusion pump manufacturer's instructions for full preparation and administration information

## Reporting side effects

Reporting side effects of your treatment is important as it allows collection of more information about the safety of EMPAVELI. If you experience any side effects (this also includes any possible side effects not listed in the Patient Information Leaflet).

You can report Adverse events by contacting:

### The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority (SFDA):

- ▶ SFDA call center: 19999
- ▶ E-mail: npc.drug@sfda.gov.sa
- ▶ Website: <http://ade.sfda.gov.sa/>

### Swedish Orphan Biovitrum AB (publ):

- ▶ Email: [drugsafety@sobi.com](mailto:drugsafety@sobi.com)
- ▶ Mobile: +966590488855

## More information

If you have any questions about your health or EMPAVELI talk to your doctor, or contact:

### Swedish Orphan Biovitrum AB (publ):

- ▶ Address: Prince Ahmed Bin Abdulaziz Road King Fahad District, 11452 PO BOX 6744 Riyadh, Saudi Arabia
- ▶ Email: [medicalinfo.me@sobi.com](mailto:medicalinfo.me@sobi.com) Mobile: +966590488855

My controlled distribution reference number:

Please write in the box your assigned CD number for reference

