

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. WHY AM I USING EMPAVELI?

EMPAVELI contains the active ingredient pegcetacoplan. EMPAVELI is used to treat adult patients with a disease called paroxysmal nocturnal haemoglobinuria (PNH); and adult and adolescent patients (aged 12 to 17 years) with diseases called complement C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN).

For more information, see Section [1. Why am I using EMPAVELI?](#) in the full CMI.

2. What should I know before I use EMPAVELI?

Do not use if you have ever had an allergic reaction to EMPAVELI or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have a serious bacterial infection that is not controlled.

Talk to your doctor about your vaccination history. You may need to receive some vaccinations before you start to use EMPAVELI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use EMPAVELI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EMPAVELI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use EMPAVELI?

EMPAVELI is intended for subcutaneous administration using a syringe system infusion pump. This means a needle is placed under the skin and the drug is slowly infused.

A doctor or nurse will show you how to self-administer EMPAVELI before you use it for the first time, if they determine that it is ok for you to give EMPAVELI to yourself.

More instructions can be found in Section [4. How do I use EMPAVELI?](#) in the full CMI.

5. What should I know while using EMPAVELI?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Use EMPAVELI exactly as your doctor tells you.• Remind any doctor, dentist, pharmacist, or other health professional you visit that you are using EMPAVELI.• Tell your doctor if you develop any signs or symptoms of an infection. See boxed warning in full CMI. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not stop using EMPAVELI without checking with your doctor. |
| Looking after your medicine | <ul style="list-style-type: none">• Store EMPAVELI at 2°C–8°C in a refrigerator. Do not freeze.• Keep the vial in the outer carton until you are ready to use it to keep it protected from light. |

For more information, see Section [5. What should I know while using EMPAVELI?](#) in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring due to approval of an extension of indications. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

As EMPAVELI blocks a part of your immune system it increases the risk of severe infections or sepsis caused by certain bacteria, such as *Streptococcus pneumoniae*, that can cause pneumonia; *Haemophilus influenzae* that can cause Hib infections; and *Neisseria meningitidis*, which can cause meningitis or a severe infection of the blood.

These infections require urgent and appropriate care as they can become rapidly fatal or life-threatening or lead to major disabilities. It is important to understand the precautions to take to reduce the risk of these infections and what to do if you are worried you may have an infection (see section 2. What should I know before I start using EMPAVELI and section 6. Are there any side effects or refer to your Patient Card).

- You must be vaccinated against these bacteria before starting EMPAVELI.
- If you start treatment with EMPAVELI less than 2 weeks after receiving any of the vaccines, you must also take antibiotics until 2 weeks after you have been vaccinated to reduce the risk of infection.
- You will need to be aware of the symptoms of these infections (see section 2. What should I know before I start using EMPAVELI and section 6. Are there any side effects or refer to your Patient Card) and notify your doctor immediately if any of the symptoms occur.
- If you cannot reach your doctor, go to the emergency department at the nearest hospital. Show your Patient Card to any doctor or nurse who treats you.

EMPAVELI[®] *(em-puh-vel-ee)*

Active ingredient(s): *pegcetacoplan (peg-set-a-koé-plan)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using EMPAVELI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EMPAVELI.**

Where to find information in this leaflet:

- [1. Why am I using EMPAVELI?](#)
- [2. What should I know before I use EMPAVELI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use EMPAVELI?](#)
- [5. What should I know while using EMPAVELI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using EMPAVELI?

EMPAVELI contains the active ingredient pegcetacoplan. EMPAVELI is a modified long-acting form of a peptide. Pegcetacoplan has been designed to attach to the C3 complement protein, which is a part of the body's defence system called the 'complement system'.

Paroxysmal nocturnal haemoglobinuria (PNH)

EMPAVELI is used to treat adult patients with a disease called paroxysmal nocturnal haemoglobinuria (PNH).

In patients with PNH, the 'complement system' is overactive and attacks their red blood cells, which can lead to low red blood counts (anaemia), tiredness, difficulty in

functioning, pain, abdominal pain, dark urine, shortness of breath, difficulty swallowing, erectile dysfunction and blood clots.

EMPAVELI attaches to and blocks the C3 protein of the complement system. This stops the body's inflammatory response from attacking and destroying PNH red blood cells. In this way, EMPAVELI improves anaemia, fatigue and other signs and symptoms of PNH.

C3 glomerulopathy (C3G) and primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)

EMPAVELI is used to treat adult and adolescent patients (aged 12 to 17 years) with diseases called complement C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (primary IC-MPGN).

Glomerulonephritis is a kidney problem where there is inflammation in the kidney. C3G and primary IC-MPGN are types of glomerulonephritis. In patients with C3G or primary IC-MPGN, the 'complement system' is overactive and when this system is not well controlled, this can result in damage to the glomerulus, a network of small blood vessels in the kidney, which filters the blood. Over time, this stops the kidneys from removing waste in the blood. This waste, if not removed from the blood, builds up in the body and may lead to kidney inflammation, damage and failure. This can lead to blood in the urine (haematuria), excess protein in the urine (proteinuria), reduced kidney function (as measured by the glomerular filtration rate [GFR]), high blood creatinine levels, tiredness and swelling (oedema) of hands, feet or ankles. This medicine has been

shown to reduce the amount of protein in the urine and can stabilise kidney function.

2. What should I know before I use EMPAVELI?

Warnings

Do not use EMPAVELI if:

- You are allergic to pegcetacoplan or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include:
 - shortness of breath, wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

- You have a serious bacterial infection which is not controlled.

Check with your doctor if you:

- Need vaccination for certain bacteria such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae*.
 - Even if you have had these vaccines in the past, you might need additional vaccinations before starting EMPAVELI. These vaccinations should be given at least 2 weeks before beginning therapy. If you cannot be vaccinated 2 weeks beforehand, your doctor will prescribe antibiotics to reduce the risk of infection until 2 weeks after you have been vaccinated.
 - Following vaccination, you may be more closely monitored by your doctor for symptoms of infection. Refer to the information below under Patient Card.
 - You should be aware that vaccines reduce the risk of serious infections, but do not prevent all serious infections. In accordance with national recommendations, your doctor might consider that you need supplementary measures to prevent infection.

Because the medicine targets the complement system, which is part of the body's defenses against infection, the use of EMPAVELI increases your risk of infections, including those caused by *Streptococcus pneumoniae*, *Neisseria meningitidis* and *Haemophilus influenzae*. These are severe infections affecting the upper respiratory tract - your nose, throat, lungs, or the linings of the brain and can spread throughout the blood and body.

Patient Card

Your doctor will give you a Patient Card about the risk of serious infection. Carry it with you at all times during treatment and for 2 months after your last EMPAVELI dose. Your risk of serious infection may continue for several weeks after your last dose of EMPAVELI. It is important to show this card to any health professional who treats you. This will help them diagnose and treat you quickly.

Symptoms of an infection are listed under Serious side effects; see Section [6. Are there any side effects?](#)

If you experience any of these symptoms, you should immediately inform your doctor and seek urgent medical attention.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. The effects of the medicine on an unborn child are not known. The use of effective contraception methods is recommended during treatment and up to 8 weeks after treatment by women who are able to get pregnant. Your doctor may do a pregnancy test before starting you on EMPAVELI. Ask your doctor for advice before taking this medicine.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if EMPAVELI passes into your breast milk.

Use in children and adolescents

Do not give this medicine to children with PNH under 18 years of age as no data are available on its safety and effectiveness in this group.

Do not give this medicine to children with C3G or primary IC-MPGN under 12 years of age as no data are available on its safety and effectiveness in this group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EMPAVELI.

4. How do I use EMPAVELI?

How much to use

Use EMPAVELI exactly as your doctor tells you.

If you use this medicine to treat PNH

The initial recommended dose for adults (18 years of age and older) with PNH is 1,080 mg twice a week. You should have the twice weekly dose on Day 1 and Day 4 of each treatment week. The dose or dosing interval should not be changed without consulting your doctor. Your doctor may

adjust your dose to 1,080 mg every third day if they deem it necessary.

If you switch to EMPAVELI from a C5 inhibitor that treats PNH, you will take EMPAVELI in addition to your current dose of C5 inhibitor for 4 weeks. After 4 weeks you should discontinue treatment with your C5 inhibitor. Follow the instructions from your doctor.

If you use this medicine to treat C3G or primary IC-MPGN

Dose for adults:

The initial recommended dose for adults with C3G or primary IC-MPGN is 1,080 mg twice a week. You should have the twice weekly dose on Day 1 and Day 4 of each treatment week.

Dose for adolescents:

The initial recommended twice a week dose for adolescents with C3G or primary IC-MPGN is based on the patient’s body weight. Your doctor will calculate your dose based on the below dosing table.

You should have the twice weekly dose on Day 1 and Day 4 of each treatment week.

| Body weight | First dose (infusion volume) | Second dose (infusion volume) | Maintenance dose (infusion volume) |
|-----------------------|-------------------------------|-------------------------------|------------------------------------|
| 50 kg and above | 1 080 mg twice weekly (20 mL) | | |
| 35 to less than 50 kg | 648 mg (12 mL) | 810 mg (15 mL) | 810 mg twice weekly (15 mL) |
| 30 to less than 35 kg | 540 mg (10 mL) | 540 mg (10 mL) | 648 mg twice weekly (12 mL) |

How to use EMPAVELI

Administer EMPAVELI using an infusion pump, carefully following the instructions below. This type of infusion can be given at home by yourself or by your caregiver after appropriate training. Administration of EMPAVELI should be done at regular twice weekly or every third day intervals. The typical infusion time is approximately 30 minutes if using 2 sites or approximately 60 minutes if using 1 site.

Step 1: Prepare for infusion

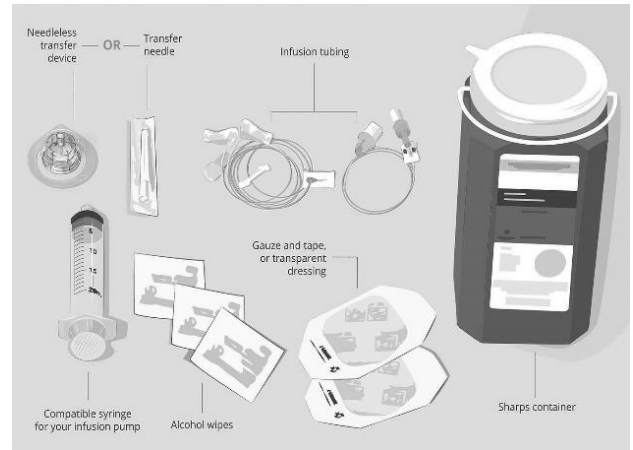
1. Prepare a clean work area. E.g., a well-lit, flat work surface area, like a table.
2. Remove a single vial carton from the refrigerator. Keep the vial in the carton at room temperature and allow it to warm up for approximately 30 minutes. Do not try to speed up the warming process
3. Gather your supplies (Figure 1).
 - 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

Thoroughly clean your work surface using an alcohol wipe.

Wash your hands thoroughly with soap and water. Dry your hands.

Figure 1 Example of Supplies



Note: Syringe system infusion pump and manufacturer’s instructions (not shown)

Step 2: Check the vial contents

Remove the vial from the carton. Carefully look at the liquid in the vial. EMPAVELI is a clear, colourless to slightly yellowish liquid. Check for particles or colour changes (Figure 2).

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 on the label has passed.

Figure 2



Step 3: Prepare and fill syringe

Remove the protective flip cap from the vial to expose the central portion of the grey rubber stopper of the EMPAVELI vial (Figure 3). Throw the cap away. Clean the stopper with a new alcohol wipe and allow the stopper to dry.

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:

1. Attach a sterile transfer needle to a sterile syringe.
2. Pull back the plunger to fill the syringe with air, which should be about 20 mL (Figure 4).
3. Push the air-filled syringe with transfer needle attached through the centre of the vial stopper.
4. Do not place the tip of the transfer needle in the solution to avoid creating bubbles (Figure 5).
5. Gently push the air from the syringe into the vial. This will inject the air from the syringe into the vial.
6. Turn the vial upside down (Figure 6).
7. With the transfer needle tip in the solution slowly pull the plunger to fill the syringe with all the EMPAVELI liquid and adjust it to the required volume (Figure 7).
8. **Double check that you have withdrawn your prescribed dose.** Any excess volume should be discarded.
9. Remove the filled syringe and the transfer needle from the vial.
10. **Do not recap the transfer needle.**
11. Unscrew the needle and throw it away in the sharps container.

Figure 3

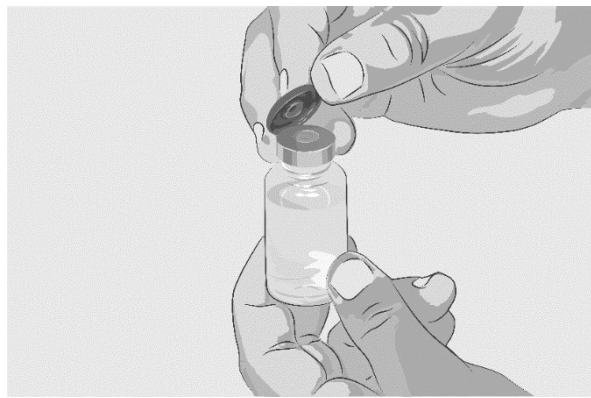


Figure 4

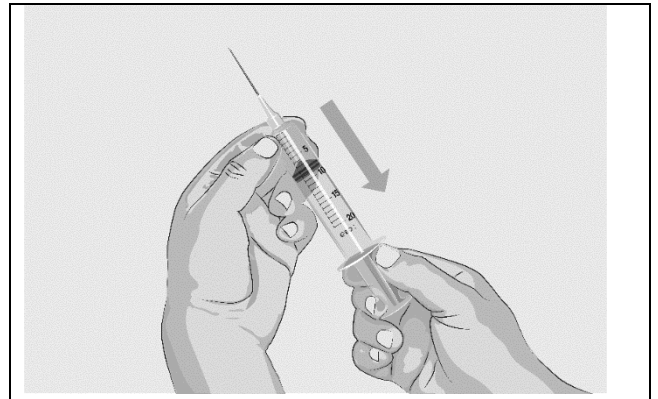


Figure 5

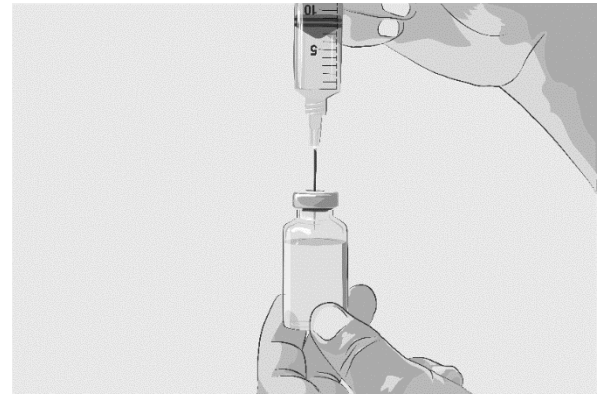
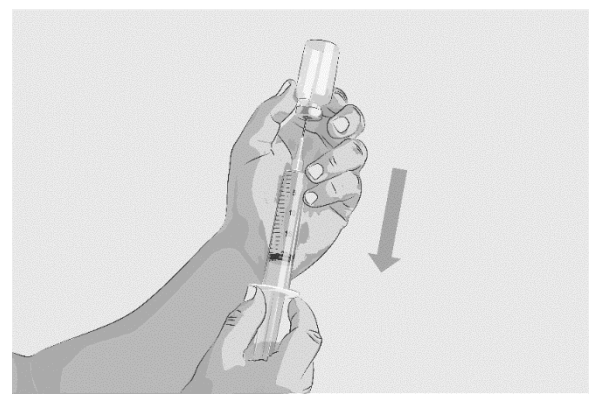


Figure 6



Figure 7



Step 4: Prepare the syringe system infusion pump and tubing.

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

Step 5: Prepare the infusion site(s)

1. Select an area on your abdomen, thighs, hips, or upper arms region for the infusion(s) (Figure 8).
2. Use a different site(s) from the last time you infused EMPAVELI. If there are multiple infusion sites, they should be at least 7.5 cm apart. Rotate infusion sites in between each infusion (Figure 9).
3. **Avoid the following infusion areas:**
 - a. **Do not infuse into areas where the skin is tender, bruised, red or hard.**
 - b. **Avoid tattoos, scars or stretch marks.**
4. Clean the skin at each infusion site(s) with a new alcohol wipe, starting at the centre and working outward in a circular motion (Figure 10).
5. Let the skin dry.

Figure 8

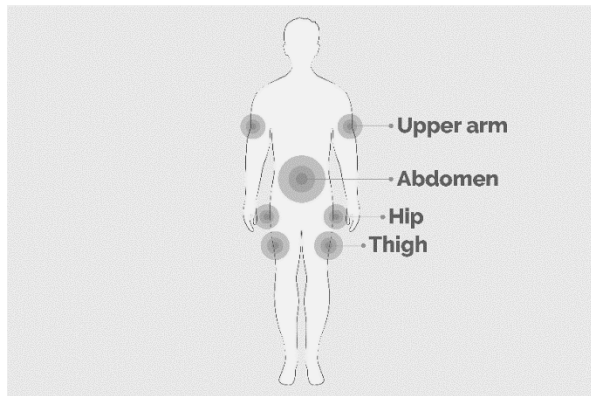


Figure 9

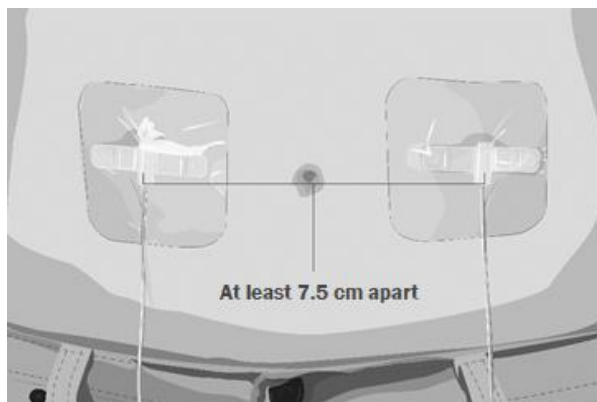
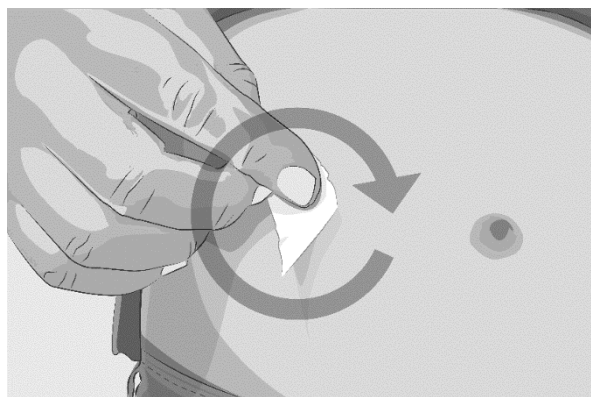


Figure 10



Step 6: Insert and secure the infusion needle(s)

1. Pinch the skin between your thumb and forefinger around the infusion site (where you intend to place the needle). Insert the needle into the skin (Figure

- 11). Follow the device manufacturer's instructions on the angle of the needle.
2. Secure the needle(s) using sterile gauze and tape or a transparent dressing placed over the infusion site(s) (Figure 12).

Figure 11

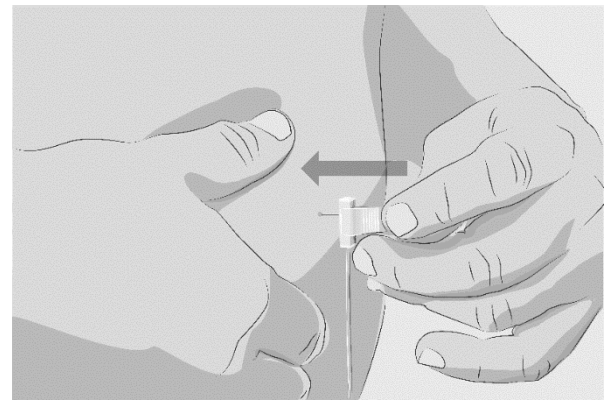
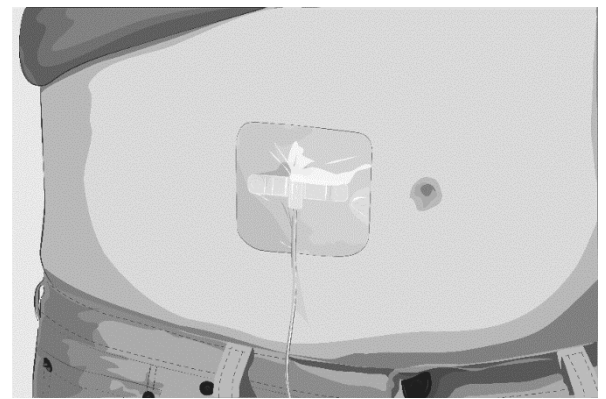


Figure 12



Step 7: Start infusion

Follow the device manufacturer's instructions to start the infusion.

Start the infusion promptly after drawing EMPAVELI into the syringe.

Step 8: Complete the infusion

Follow the manufacturer's instructions to complete the infusion.

Step 9: Record infusion

Record your treatment as directed by your healthcare provider.

Step 10: Clean up

1. After the infusion is complete, remove the dressing and slowly take out the needle(s). Cover the infusion site with a new dressing.
2. Disconnect the infusion set from the pump and discard into the sharps container (Figure 13).
3. Throw away all used disposable supplies.
4. Clean and store the syringe system infusion pump according to the device manufacturer's instructions.
5. EMPAVELI is for single use in one patient only. Discard any residue left in the vial and the empty vial as recommended by your healthcare provider.

Figure 13



Be sure to tell your doctor or healthcare provider about any problems you have with your infusion.

If you forget to use EMPAVELI

If you miss a dose of EMPAVELI, and you have not yet taken your next dose, then take the missed dose as soon as possible. Then continue your regular dosing schedule.

Do not take 2 doses on the same day. The missed dose and next dose may be taken on 2 consecutive days.

If you have any questions, contact your doctor.

If you use too much EMPAVELI

The effects of overdose of EMPAVELI are not known.

If you think that you have used too much EMPAVELI, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using EMPAVELI?

Things you should do

PNH is a life-long condition and so it is expected that you will use this medicine for a long-time.

It is recommended that you keep a record of doses taken. Be sure to take the record with you each time you visit your doctor as they may ask to see it.

Remind any doctor, dentist, pharmacist, or other health professional you visit that you are using EMPAVELI.

Keep appointments with your doctor or clinic. Have any tests when your doctor tells you to.

Call your doctor straight away if you:

- Have had an allergic reaction to EMPAVELI, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing, or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching, or hives on the skin.

Things you should not do

Do not stop using this medicine suddenly.

Do not stop taking EMPAVELI unless your doctor tells you to do so.

If your doctor decides to stop EMPAVELI for treatment of PNH

If your doctor decides to stop your treatment with EMPAVELI, follow their instructions for how to stop. Your doctor will monitor you closely for at least 8 weeks after stopping treatment with EMPAVELI for any signs of the breakdown of red blood cells due to PNH.

Symptoms or problems that can happen due to red blood cell breakdown are listed under Serious side effects; see Section [6. Are there any side effects?](#)

If your doctor decides to stop EMPAVELI for treatment of C3G or primary IC-MPGN

C3G and primary IC-MPGN are lifelong conditions and so it is expected that you will use this medicine for a long time. If your doctor wishes you to stop using the medicine, follow their instructions for how to stop.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how EMPAVELI affects you.

This medicine has no or negligible influence on the ability to drive and use machines.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store EMPAVELI in the refrigerator and keep the vials inside the cartons until immediately before use to protect them from light.

Keep EMPAVELI where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <p>Reactions at the site of administration or infusion including:</p> <ul style="list-style-type: none"> • redness • swelling • itching • bruising • hardening of the infusion site <p>Other less serious side effects include:</p> <ul style="list-style-type: none"> • feeling of weakness • diarrhoea • abdominal pain • back pain • pain in the arms, hands, legs, feet • headache • high blood pressure • cough • tiredness • anxiety • abdominal swelling • stomach flu (gastroenteritis) • nosebleed • mouth and throat pain • common cold • infection of the nose, throat, or airways • urinary tract infection • cold sore (oral herpes) • rash or hives | <p>Speak to your doctor if you have any of these less serious side effects and they don't go away or they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|---|--|
| <p>Infections</p> <p>Symptoms of infections include:</p> <ul style="list-style-type: none"> • high heart rate • shortness of breath • extreme pain or discomfort • headache with nausea or vomiting • headache and a fever • headache with a stiff neck or stiff back • confusion • fever and a rash • fever with or without shivers or the chills • muscle aches with flu-like symptoms • clammy skin • eyes sensitive to light <p>In PNH, destruction of red blood cells if pegcetacoplan is stopped suddenly.</p> | <p>Call your doctor straight away or go to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>Show any doctor, dentist, pharmacist, or other health professional you visit your Patient Card.</p> |

| Serious side effects | What to do |
|---|------------|
| <p>Symptoms of destruction of red blood cells include:</p> <ul style="list-style-type: none"> • tiredness • shortness of breath • blood in the urine • stomach-area (abdomen) pain • drop in the number of your red blood cell count • blood clots (thrombosis) • trouble swallowing • erectile dysfunction in males <p>Other serious side effects may include:</p> <ul style="list-style-type: none"> • anaphylactic reaction or shock • fewer platelets in the blood (thrombocytopenia) which may cause bleeding or bruising more easily than normal • decrease in kidney function where you may pass little or no urine | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What EMPAVELI contains

| | |
|---|--|
| Active ingredient (main ingredient) | Pegcetacoplan |
| Other ingredients (inactive ingredients) | Sorbitol Glacial acetic acid Sodium acetate trihydrate Sodium Hydroxide Water for injections |
| Potential allergens | Sorbitol |

Do not take this medicine if you are allergic to any of these ingredients.

What EMPAVELI looks like

EMPAVELI is a clear, colourless to slightly yellowish liquid contained in a 20 mL glass vial. Solutions that are cloudy or have particles or colour change should not be used. (Aust R 346216).

EMPAVELI comes in cartons of 1 or 8 vials

Who distributes EMPAVELI

Swedish Orphan Biovitrum Pty Ltd

Suite 3, Level 2, Building D,

12-24 Talavera Road

Macquarie Park, NSW 2113

<https://au.sobi.com>

Medical enquiries: 1800 570 605.

This leaflet was prepared in December 2025.