AN INTRODUCTION TO EMPAVELI®(pegcetacoplan)

Guide for patients and caregivers

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

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 of the package leaflet for how to report side effects.

Patient Information Leaflet can be found in pocket on back inside cover

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EMPAVELI®
(pegcetacoplan)

Contents

Introduction

This booklet has been given to you because you, or someone in your care, has been prescribed EMPAVELI.

Injecting yourself or someone in your care may seem difficult when you first begin, but there are tips and tricks that might make it easier to incorporate the administration into your daily routine. As you read through this booklet, keep in mind that every patient is different. You should talk to your doctor about how this information applies to you.

Your doctor will fill out and provide you with a Patient Card. Please use it to quickly reference your treatment, doctor's phone number, and important safety information.

Your doctor or nurse can answer any specific questions about the diagnosis and treatment management.

What is EMPAVELI?

EMPAVELI is a medicine that contains the active substance pegcetacoplan. Pegcetacoplan has been designed to attach to the C3 complement protein, which is a part of the body's defences against infection called the 'complement system'. 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). The treatment is given twice weekly by infusion under the skin.

Patient Card:

You will receive a Patient Card from your doctor.

- This card will have your unique Controlled Distribution (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 serious bacterial infection even if you do not have your card on you.

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. These are severe bacterial infections affecting your nose, throat and lungs or the linings of the brain and can spread throughout the blood and body. Serious bacterial infections may quickly become life-threatening and cause death 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 a serious 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 serious infections. However, vaccines do not prevent all serious infections.
- Your doctor will ensure that you receive vaccination against the bacteria Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae according to applicable local guidelines 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.
- You should receive these vaccinations 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, and which should continue for 2 weeks after your vaccination.
- When you have been vaccinated your doctor will be given a Controlled Distribution (CD) reference number. Your doctor should write this number onto your Patient Card. You will need to show this number to your pharmacist before they can dispense EMPAVELI

Risk of allergic reactions

Allergic reactions may appear in some patients.

Discontinue EMPAVELI infusion and seek medical help immediately, in case you experience any of these signs and symptoms of an allergic reaction:

- Difficulty breathing
- Chest pain or chest tightness
- Feeling dizzy/faint
- Severe itching of the skin or raised lumps on the skin
- Swelling of the face, lips, tongue and /or throat, which may cause difficulty in swallowing or collapse

Risk of intravascular haemolysis after drug discontinuation

- If you plan to stop treatment with EMPAVELI, ensure to discuss this beforehand with your doctor.
- It is very important to make sure that you/the patient in your care do/does not miss or postpone any scheduled treatments.
- If EMPAVELI treatment is stopped completely, or postponed (or if treatments are missed), there is a risk that one of the serious features of PNH, haemolysis, could occur. Haemolysis is when red blood cells, which carry oxygen through your body, break apart. Haemolysis is connected to various symptoms of PNH, such as:
    - Tiredness (Fatigue)
    - Dark Urine (Haemoglobinuria)
    - Tummy (Abdominal) pain
    - Breathlessness
    - Formation of blood clots (Thrombosis)
    - Difficulty in swallowing
    - Erectile dysfunction
- Notify your doctor immediately if you notice any sign or symptom of haemolysis.

Recommendations for contraception

The effects of EMPAVELI on an unborn child are not known. The use of effective contraception is recommended during treatment and up to 8 weeks after treatment by women of childbearing potential. Ask your doctor for advice before taking this medicine.

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, you can administer your twice-weekly dose yourself.

EMPAVELI comes in a glass vial, which needs to be kept in the refrigerator in the original carton to protect the liquid from light. One vial contains the dose for one infusion.

You can find a detailed description on how to self-administer in the EMPAVELI Patient Information Leaflet and the infusion pump manufacturer's instructions or in the video link below.

Description of the modalities used for self-infusion:

For your infusion you will need:

Syringe system infusion pump and manufacturer's instructions (not shown).

A. Syringe system infusion pump

B. Compatible syringe

C1. Transfer needle OR

C2. Needleless transfer device to draw up product from the vial

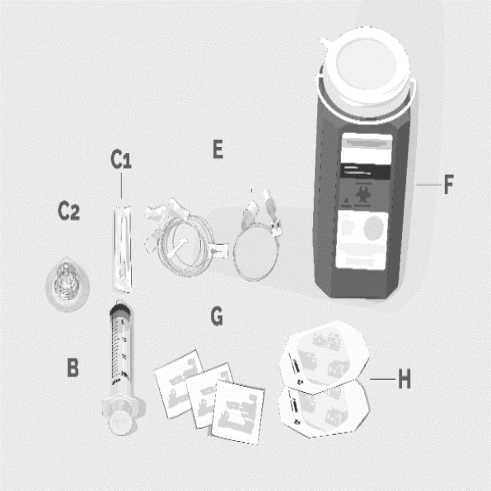
D. Infusion set (not shown; varies according to device manufacturer's instructions)

E. Infusion tubing and Y connector (if required)

F. Sharps container

G. Alcohol wipes

H. Gauze and tape, or transparent dressing



For illustration only. The supplies you receive may look different

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), in particular serious infections with encapsulated bacteria, severe hypersensitivity reactions, or haemolysis after drug discontinuation, inform your doctor, pharmacist or nurse.

You can report side effects by contacting your doctor or by contacting:

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

- SFDA call center: 1999
- E-mail: npc.drug@sfda.gov.sa
- Website: http://ade.sfda.gov.sa/

Swedish Orphan Biovitrum AB (publ):

- Email: pv-ksa@sobi.com
- Website: Sobi in Middle East | Focus on Rare Diseases
- Phone no: +966 800 850 1523

More information

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

Swedish Orphan Biovitrum AB (publ):

- Medical Information: pv-ksa@sobi.com

My Controlled Distribution (CD) reference number:

Please write in the box your assigned CD number for reference

NP- 43528
July 2025

Make a note of any questions you have for your next visit to the doctor