

Keep this card with you at all times
show it to any healthcare provider involved
in your health care and if you go to hospital.

NP-20036

Patient Card



This document is approved by the executive
directorate of pharmacovigilance, at SFDA.

INFORMATION FOR THE TREATING PHYSICIAN

This patient has been prescribed EMPAVELI®
(pegcetacoplan), which may increase the patient's
risk of bacterial infections such as *Streptococcus*
pneumoniae, *Neisseria meningitidis*, and
Haemophilus influenzae type B infections.

- Bacterial infections may become life-threatening if not recognized and treated early.
- Closely monitor patients for early signs and symptoms of infection and evaluate immediately if infection is suspected. Promptly treat known infections.
- Contact the patient's prescribing physician as soon as possible if any infection is suspected.

For more information about EMPAVELI®, please refer to the full Summary of Product Characteristics.

To report adverse events or safety concerns, contact:

**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
- Mobile: +966590488855

Show this card to any healthcare provider involved in your care.

Patient Name

Controlled distribution (CD) reference number

Prescriber Name

Prescriber Phone

Patients receiving EMPAVELI® should carry this card with them at all times.

EMPAVELI® may increase your risk of getting infections. Infections may become life-threatening if not recognized and treated early. Call your healthcare provider 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

Always keep this card with you during treatment and for 2 months after your last dose. Your risk of infections may continue for several weeks after your last dose.

- 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.