

Patient Card

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

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

Information for the Treating Physician

This patient has been prescribed EMPAVELI® (pegcetacoplan), EMPAVELI is a complement inhibitor indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). EMPAVELI may increase the patient's risk of serious bacterial infections such as Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B infections.

- Serious Bacterial infections may become rapidly life-threatening or fatal if not recognized and treated early.
- Closely monitor patients for early signs and symptoms of serious infection and evaluate immediately if infection is suspected. Promptly treat known infections.
- Contact the patient's prescribing physician as soon as possible if any serious 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@sfd.gov.sa
- Website: <http://ade.sfd.gov.sa/>



Swedish Orphan Biovitrum AB (publ):

- Email: pv-ksa.a@sobi.com

Patients receiving EMPAVELI® should carry this card with them at all times. Patients must show the Controlled Distribution Reference Number to pharmacists before EMPAVELI® can be dispensed

EMPAVELI® may increase your risk of getting serious and life-threatening infections. Serious Infections may quickly become life-threatening and cause death 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 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

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

Patient Name

Controlled distribution (CD) reference number

Prescriber Name

Prescriber Phone

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

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