



# EMPAVELI® (pegcetacoplan) Patient Card

- Important Information For Patients Taking Pegcetacoplan
- 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
- Show this card to any healthcare provider involved in your care.
- This Document Is Approved By The Executive Directorate Of Pharmacovigilance, At Sfd.

## 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), and treatment of adult and adolescent patients aged 12 years and older with a kidney disease called complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN). 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.

## Information for patients

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.

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**Patient Name**

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**Controlled distribution (CD) reference number**

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**Prescriber Name**

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**Prescriber Phone**

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](mailto:npc.drug@sfda.gov.sa)
- Website: <http://ade.sfda.gov.sa>



**Swedish Orphan Biovitrum AB (publ):**

- Email: [pv-ksa@sobi.com](mailto:pv-ksa@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