Important Risk Minimization Information for "Healthcare Professionals"

EMPAVELI® (pegcetacoplan) Annual Vaccination Reminder

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

Dear Dr,

This communication is to remind you that patients being treated with EMPAVELI® may be predisposed to serious infections caused by encapsulated bacteria including Neisseria meningitidis, Streptococcus pneumoniae, and Haemophilus influenzae. To reduce the risk of infection, all patients must be vaccinated against these bacteria according to applicable local guidelines at least 2 weeks prior to receiving EMPAVELI®, unless the risk of delaying therapy outweighs the risk of developing an infection.

Please ensure to provide Sobi with the completed copies of vaccination confirmation form before first dose, for any new patient.

Once the written vaccination confirmation is received Sobi is sharing with treating physician a unique Control Distribution reference number (CDRN) to allow EMPAVELI® Dispensation.

Sobi is committed to ensure sending vaccination annual reminders to all register treating HCPs.

Patients with known history of vaccination

Before receiving treatment with EMPAVELI®, in patients with a known history of vaccination, it should be ensured that patients have received vaccines against encapsulated bacteria including Streptococcus pneumoniae, Neisseria meningitidis types A, C, W, Y, and B, and Haemophilus influenzae Type B within 2 years prior to starting EMPAVELI® or according to applicable local guidelines.

Revaccination of patients

Patients that continue to be treated with EMPAVELI® must be revaccinated periodically, depending on the duration of protection provided by the vaccines they have received.

Please check that your patients who may need revaccination receive their vaccines according to applicable local guidelines to enable them to continue treatment.

For further details and information related to EMPAVELI® please refer to SPC/PIL.

Adverse event reporting

Reporting suspected adverse events is important as it allows for continued monitoring of the benefit/risk balance of EMPAVELI. Report all adverse events including those of serious infections with encapsulated bacteria, severe hypersensitivity reactions and intravascular haemolysis after discontinuation of the medicinal product by contacting:

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