

Vaccination Confirmation Form

EMPAVELI® (pegcetacoplan) controlled distribution programme

Instructions

1. This form must be completed for each patient to indicate that they have received vaccination or antibiotic treatment prior to initiation of treatment with EMPAVELI® (pegcetacoplan).
2. Please send the completed form to Sobi Customer services who will process the form and provide you with a Controlled Distribution Reference Number to indicate that confirmation has been provided that the patient has received vaccination or antibiotic treatment.
3. This reference number is unique for each patient and must be written onto the Patient Card.
4. Patients must show this number to a dispensing pharmacist (along with a valid prescription) before the drug can be dispensed.

Prescriber information

Name of Prescriber:

Hospital:

Phone Number:

Address:

Fax Number:

City:

Country:

Email:

Prescriber Declaration (Patient Education and consenting)

I confirm that I have explained EMPAVELI® treatment to the patient/parent(s)/legal guardian(s) and I will give the patient/parent(s)/legal guardian(s) all necessary information, including the "Patient Card" and "Patient Guide" before initiating treatment with EMPAVELI®. I have informed the patient on the Privacy Notice and obtained the patient's agreement to provide their initials, date of birth and confirmation of receipt of vaccination or antibiotic treatment for the purpose of generating a Controlled Distribution Reference number.

Patient Information

Patient Initials:

Date of Birth (dd/mm/yyyy):

Confirmation of Vaccination status

I confirm that the patient has received vaccination against Streptococcus pneumoniae, Neisseria meningitidis types A, C, Y, W135, and type B, and Haemophilus influenzae type B within 2 years prior to starting EMPAVELI® or according to applicable local guidelines. I understand that vaccination must have been given at least 2 weeks before the administration of the first dose of EMPAVELI® or if immediate treatment is needed, that the patient has received prophylactic antibiotics from at least the 1st day of EMPAVELI® treatment and until 2 weeks after vaccination. I understand that I will receive annual reminders regarding patient vaccination status, and I confirm that I will review the need for re-vaccinations according to applicable local guidelines.

Name of Prescriber:

Date (dd-mmm-yyyy):

I hereby declare that I have read and fully understood the information provided by means of the Privacy Notice regarding the processing of my personal data by Sobi and that I consent to Sobi holding my name and contact details in accordance with the Privacy notice.

Signature:

Please send this completed form to Sobi Customer Services: pv-me@sobi.com

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@sobi.com

For Sobi Office use – please add number and return a copy of this form to the prescriber.

Controlled Distribution Reference Number (CDRN)

SOBI-PEG-

Note to prescriber – please give this number to your patient (the number needs to be written on their Patient Card). The number confirms vaccination which is needed to allow dispensing of Empaveli.

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA – Version 3 - March 2026
NP-48819