

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 which proves that the patient is vaccinated (whilst maintaining patient confidentiality)
3. This 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 also obtained the patient's agreement to collect their initials and date of birth for the purpose of generating a Controlled Distribution Reference number.

Patient Information

The following information is needed for setting up the Controlled Distribution Reference Number

Patient Initials

Date of Birth (dd/mm/yyyy)

Confirmation of Vaccination status

I confirm that the patient received a vaccination against Streptococcus pneumoniae, Neisseria meningitidis types A, C, Y, W and type B, and Haemophilus influenzae type B or has received prophylactic antibiotics according to the current national 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 was needed, the patient received prophylactic antibiotics from at least the 1st day of EMPAVELI treatment and until 2 weeks after vaccination.

Name of Prescriber:

Date: (dd-mmm-yyyy):

By completing this form, you consent to Sobi holding your name and contact details.

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

Version 01, November 2021

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

For Sobi Office use

Please add number and return a copy of this form to the prescriber.

Controlled Distribution Reference Number

Note to prescriber

Please give this number to your patient (the number needs to be written on their Patient Card).

The number confirms vaccination and is needed to allow dispensing of EMPAVELI.

NP-20036