NOVARTIS

Vaccination Confirmation Form

Controlled Access of Fabhalta® ▼ (iptacopan)

In accordance with the risk management plan as required by Medicines and Healthcare products Regulatory Agency ("**MHRA**"), iptacopan can only be dispensed once Novartis receives written confirmation that each patient has received vaccination against *N. meningitidis* and *S. pneumoniae* infections and/or receipt of prophylactic antibiotic treatment (in accordance with national guidelines).

To comply with these regulatory requirements, a unique patient identification number ("**Patient ID**") for each patient must be obtained from Novartis' designated Commercial Operations and Customer Care Manager before starting treatment with iptacopan for such patient. This Patient ID can be obtained by submitting the completed form below. Please submit the form by email to commercial.team@novartis.com

The Patient ID for each patient must be noted on the prescription and the patient safety card for such patient.

Novartis are required to collect personal data to monitor the safety of medicinal products and medical devices, respond to queries and complaints, and comply with legal and regulatory obligations. Any personal data will be processed in accordance with the applicable data privacy notice available at https://www.novartis.com/uk-en/privacy-policy, which may be updated by Novartis from time to time.

If you have any queries in relation to any Patient ID, please seek assistance by email commercial.team@novartis.com

Confirmation of vaccination and/or antibiotic prophylaxis

Healthcare Professional (HCP) Details	
Name of Prescribing HCP:	
Clinic / Practice:	
Address:	
E-Mail:	

Patient Details	
Initials (First Name / Last Name):	
Date of Birth (DD/MM/YYYY):	

By signing this form, I, as the prescribing HCP, confirm that:

(1) The patient above or his/her legal representative has been informed about treatment with iptacopan and all necessary information including the Patient and Caregiver Guide and Patient Safety Card has been handed to the patient before the treatment.

(2) The patient above is vaccinated against *N. meningitidis* and *S. pneumoniae* and/or will receive antibiotic prophylaxis until 2 weeks after vaccination in accordance with national guidelines before starting treatment.

(3) The prescription of iptacopan for the patient above is within the scope of the Summary of Product Characteristics (SmPC) of iptacopan as approved by the MHRA (including the patient above being at or over 18 years of age).

Signature	
Date:	Signature:

To be filled by Controlled Access Provider	
Patient ID:	Date:

Please keep a copy of this form with the Patient ID and note the Patient ID on the prescription and the patient safety card, each for the patient of whom the Patient ID represents.

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report or alternatively email medinfo.uk@novartis.com or call 01276 698370.