NOVARTIS

Vaccination Confirmation Form

Controlled Access of FABHALTA ▼ (Iptacopan)

In accordance with the risk management plan as required by Therapeutic Goods Administration (TGA), FABHALTA® 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). Vaccination should be administered at least two weeks prior to the start of treatment. If immediate treatment is necessary, patients should be vaccinated as soon as possible and receive antibiotic prophylaxis for up to 2 weeks after the last vaccination.

Novartis has established a controlled dispensation system that records confirmation and generates a unique patient identification number (Pat.-ID) for each patient. To create a Pat.-ID for the first time, complete this form and email to VCF@FABHALTA.com. You will receive an email with Pat.-ID and login credentials to manage your patient in the online portal at www.fabhalta-ID.com/au. For additional patients, you can create a Pat.-ID instantly by completing an electronic VCF in the portal. For assistance please contact a Novartis representative or email medinfo.phauno@novartis.com.

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 www.novartis.com.au/privacy-policy which may be updated by Novartis from time to time. For any queries in relation to a Patient ID, please speak to your local Novartis representative or email a query to medinfo.phauno@novartis.com.

Confirmation of vaccination and/or antibiotic prophylaxis

Physician Details			**Patient Details**	
Name of Treating Physician			Initials (First Name / Last Name)	
Clinic / Practice			Day of Birth	
Address			Month of Birth	
Fax	E-Mail		New or existing patient	☐ **New** ☐ **Existing**
Preferred Contact Route	☐ **E-Mail** ☐ **Fax**		Current Patient ID (for existing patients)	

With my legally binding signature, I confirm that:

(1) The patient above or his/her legal representative has been informed about treatment with FABHALTA® 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 has been vaccinated against *Neisseria meningitidis* and *Streptococcus pneumoniae* according to the applicable national guidelines before the start of treatment and/or is receiving antibiotic prophylaxis. I am aware that vaccination should be administered at least two weeks before the start of treatment, or if immediate treatment is necessary, the patient should be vaccinated as soon as possible and receive antibiotic prophylaxis for up to 2 weeks after the last vaccination. If available, vaccination against *Haemophilus influenzae* type B is recommended."

(3) The prescription of iptacopan for the patient above is within the scope of the Australian Product Information as approved by the TGA (including the patient above being at or over 18 years of age).

(4) I will be reminded once a year via email, using the contact information provided above, about the required follow-up vaccinations according to the national vaccination guidelines.

Signature			**To be filled by Service Provider**	
Date	Signature		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.

See TGA approved Product Information before prescribing. TGA approved Product Information available on request.
For up-to-date Product Information go to https://www.novartis.com.au/products/healthcare-professionals/products

Adverse events should be reported. If you are reporting an adverse event, please submit to Patient Safety online at https://www.novartis.com/report or email patientsafety.aunz@novartis.com or call 1800 814 677 (Australia) / 0800 650 555 (New Zealand).

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