

Patient safety card

Important safety information
for patients taking iptacopan

This material has been developed by Novartis Ireland Ltd. and is intended only for patients with paroxysmal nocturnal haemoglobinuria (PNH), who have been prescribed iptacopan.

▼ This medicinal product is subject to additional monitoring. If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side effects, you can help provide more information on the safety of this medicine. You can report side effects directly to HPRA Pharmacovigilance at www.hpra.ie. Side effects can also be reported to Novartis preferably at www.novartis.com/report, by emailing drugsafety.dublin@novartis.com or by calling (01) 2080 612.

This material does not replace the patient information leaflet (PIL) that comes with your medication. You should read the PIL carefully before you start taking this medicine because it contains important information for you.

During treatment, your immune system has a lower ability to fight certain bacterial infections (specifically from encapsulated bacteria).¹

These infections may cause meningitis, pneumonia, sepsis, or other life-threatening infections. They can cause death if not recognised and treated early.¹

Keep this card with you at all times during treatment and for 2 weeks after your last dose, and show it to any healthcare professional involved in your care.

Contact your doctor immediately or call 112 or 999, and show this card, if you experience any of the following signs and symptoms of serious infection:

- **Fever**

- With or without shivers or chills
- With a headache
- With a rash
- With chest pain and cough
- With breathlessness/ fast breathing
- With high heart rate

- **Headache**

- With feeling sick (nausea) or vomiting
- With a stiff neck or stiff back

- **Confusion**

- **Body aches with flu-like symptoms**

- **Clammy skin**

- **Eyes sensitive to light**

Information for healthcare professionals

This patient has been prescribed FABHALTA® (iptacopan) for paroxysmal nocturnal haemoglobinuria (PNH).

Iptacopan may increase the patient's susceptibility to serious infections caused by encapsulated bacteria (*Neisseria meningitidis*, *Streptococcus pneumoniae* and *Haemophilus influenzae* Type B). These infections include meningitis, pneumonia and sepsis. Serious infections may rapidly progress and may become life-threatening or fatal if not recognised and treated early.



Recognise

Immediately evaluate if bacterial infection is suspected.



Treat

Immediate use of antibiotics is vital in cases of suspected meningitis, pneumonia or sepsis.



Inform

Please call the patient's prescribing doctor as soon as possible using the number provided on the last page of this card to receive further information.

Please also note that any adverse events discussed in the course of your consultation should be reported.

For more information, please refer to the Summary of Product Characteristics for FABHALTA®, available on www.medicines.ie, and where further safety information can be found.

Reference: 1. Fabhalta (iptacopan) Patient Information Leaflet, available at www.medicines.ie

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FABHALTA® EU RMP Patient Safety Card, version 1.0

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Patient name:

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Patient ID / Unique Identifier:

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Blood group:

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Emergency contact name and number:

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Prescribing doctor name and number:

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