

Patient safety card

Important safety information for
patients taking **FABHALTA**® (iptacopan)

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

Please report suspected side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

By reporting suspected side effects, you can help provide more information on the safety of this medicine.

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).

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

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 999 and show this card in case 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 & 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 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 consultation with your patient should be reported.

Please report suspected side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

By reporting suspected side effects, you can help provide more information on the safety of this medicine.

Please refer to the Summary of Product Characteristics for iptacopan, where further safety information can be found.

© 2024 Novartis Pharmaceuticals UK Ltd. All rights reserved.

UK | August 2024 | 431517

Approved by MHRA August 2024

Patient name:

.....

Patient ID (controlled access):

.....

Blood group:

.....

Emergency contact name and number:

.....

Prescribing doctor name and number:

.....

 **NOVARTIS**