Patient and caregiver guide to treatment with 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 and their caregivers. This guide aims to provide you with important safety information for iptacopan.

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.

Please keep this document for future reference.

Please report suspected side effects to the MHRA through the Yellow Card scheme.
You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

If you have any questions or concerns about iptacopan, speak with a healthcare professional.

NOVARTIS

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Introduction

This guide has been developed to provide you with important safety information for iptacopan.

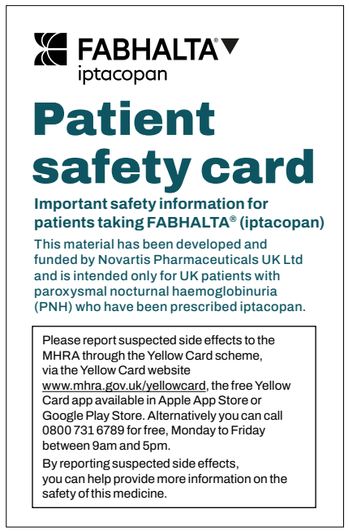
If you have any questions or concerns about this medicine or your health and wellbeing, please speak with your treating doctor, nurse or pharmacist/other healthcare professional (HCP).

Prescribing doctor: .....

Nurse: .....

Pharmacist: .....

Other HCP: .....


FABHALTA® iptacopan

Patient safety card

Important safety information for patients taking FABHALTA® (iptacopan)

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Your patient safety card

When you are first prescribed iptacopan, you are given a patient safety card.

This wallet-sized card contains important safety information about the risk of infection while taking iptacopan, and what to do if you get certain signs or symptoms.

It also contains the emergency contact details of your doctor or hospital. The contact details will be added to the card by your doctor.

Keep this card with you at all times during treatment, and for a period of 2 weeks following your last iptacopan dose in case of an emergency. Show this card to any healthcare professional involved in your care so they know that you are being treated with iptacopan. This will help them to diagnose and treat you correctly.

If you have not received a patient safety card, please contact your doctor or nurse.

A patient identification (ID) number was also created for you by your doctor when you were first prescribed iptacopan. This should be written on your patient safety card. Share this number with your pharmacist to receive iptacopan.

My patient ID: .....

What is in this guide?

Please refer to the package leaflet for more information.

What important safety risks do I need to know about?

Risk of infections

Iptacopan reduces your body's defences against infection, specifically the activity of the complement system, which may increase the risk of certain serious infections.

This includes infections caused by specific types of bacteria called "encapsulated bacteria". Examples of these are *Neisseria meningitidis, Streptococcus pneumoniae* and *Haemophilus influenzae* type B.

Infections caused by these bacteria affect the nose, throat and lungs or the linings of the brain and can spread throughout the blood and body. Serious bacterial infections may quickly become life-threatening and cause death if not identified and treated early.

The signs and symptoms of serious infection you need to look out for are:

- **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**
  - 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**

Contact your doctor in case you experience any of the signs and symptoms above and seek immediate medical care at the nearest hospital.

Carry your safety card with you and present it if the healthcare professional contacted is not the one involved in your PNH treatment.

Vaccinations and prophylactic antibiotic treatment

Vaccinations reduce the risk of certain serious bacterial infections.

Your doctor will inform you about which vaccinations you need before starting treatment with iptacopan. You may need additional antibiotic treatment to prevent infection.

Vaccines you must be given are:

- **Meningococcal vaccine**
- **Pneumococcal vaccine**

Vaccine you may be given:

- ***Haemophilus influenzae* type B vaccine**

These vaccines can protect you against serious diseases such as meningitis, pneumonia, and sepsis. Multiple different vaccinations are required to provide the most protection.

Even if you have had these vaccinations before, your doctor will advise you on whether you need to have the same vaccination again or if you require booster vaccinations before starting iptacopan treatment.

You must be given all of these vaccinations at least 2 weeks before you start treatment with iptacopan.

If vaccination in this time is not possible, your doctor will prescribe antibiotics to help lower the chance of developing bacterial infections. You will only be supplied iptacopan if your doctor or pharmacist confirms that you are receiving the correct vaccinations or antibiotics.

To help prevent serious infections, it is important that your vaccines are up to date. Your doctor will make sure that you are revaccinated as needed. Please be aware, vaccinations reduce the chances of developing serious infections, but may not prevent all serious infections.

Please refer to the package leaflet for more information.

Risk of haemolysis after discontinuing iptacopan

Discontinuing iptacopan may increase the risk of serious breakdown of red blood cells (haemolysis). It is important that you adhere to your prescribed treatment regimen.

Possible signs and symptoms of haemolysis you need to look out for are:

- **Tiredness**
- **Blood in the urine**
- **Pain in the stomach (abdomen)**
- **Shortness of breath**
- **Trouble swallowing**
- **Erectile dysfunction (impotence)**
- **Blood clots (thrombosis)**

Seek immediate medical attention if you notice any signs or symptoms of haemolysis.

If you want to stop taking iptacopan, talk to your doctor before discontinuing treatment. If you miss a dose of iptacopan, take it as soon as you can, even if it is close to the next dose.

How should I report side effects?

Like all medicines, this medicine can cause side effects, although not everybody experiences them.

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What is a Post-Authorisation Safety Study (PASS)?

A post-authorisation safety study (PASS) is a study that is carried out after a medicine has been approved and aims to collect further information on a medicine's long-term safety. For iptacopan, data for the PASS will be collected from selected healthcare centres in Europe and other countries.

If your healthcare team participates in an organised data collection on iptacopan, they will inform you about this and will provide you with comprehensive information about the study. You will have the option to provide your consent to sharing your data by signing a form. If you choose to take part, your healthcare team or nurse will collect some of your medical information, including your diagnosis, treatment and medical history, and adverse events while on treatment.

Your participation is completely voluntary, and any data that could potentially identify you directly or indirectly will be made anonymous. Furthermore, you can withdraw your consent at any time.

The information provided is for educational purposes only and is not intended to replace discussions with your treating healthcare team.

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