FABHALTA - Resources and FAQs - MOP

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Resources and FAQs

This page is intended for UK patients who have been prescribed iptacopan for paroxysmal nocturnal haemoglobinuria.

The information on this website does not replace the patient information leaflet which comes with your medication. Please always refer to your patient information leaflet for more information. If you have any questions, ask your doctor or care team. Connected – Stronger Together is a patient support programme organised and funded by Novartis.

Resources and FAQs

The National PNH Service

The **National PNH Service** is a world-renowned UK-based service, with expertise in managing patients with PNH. The service provides education to further the knowledge of diagnosis and management of PNH, with the aim to improve patient care worldwide.

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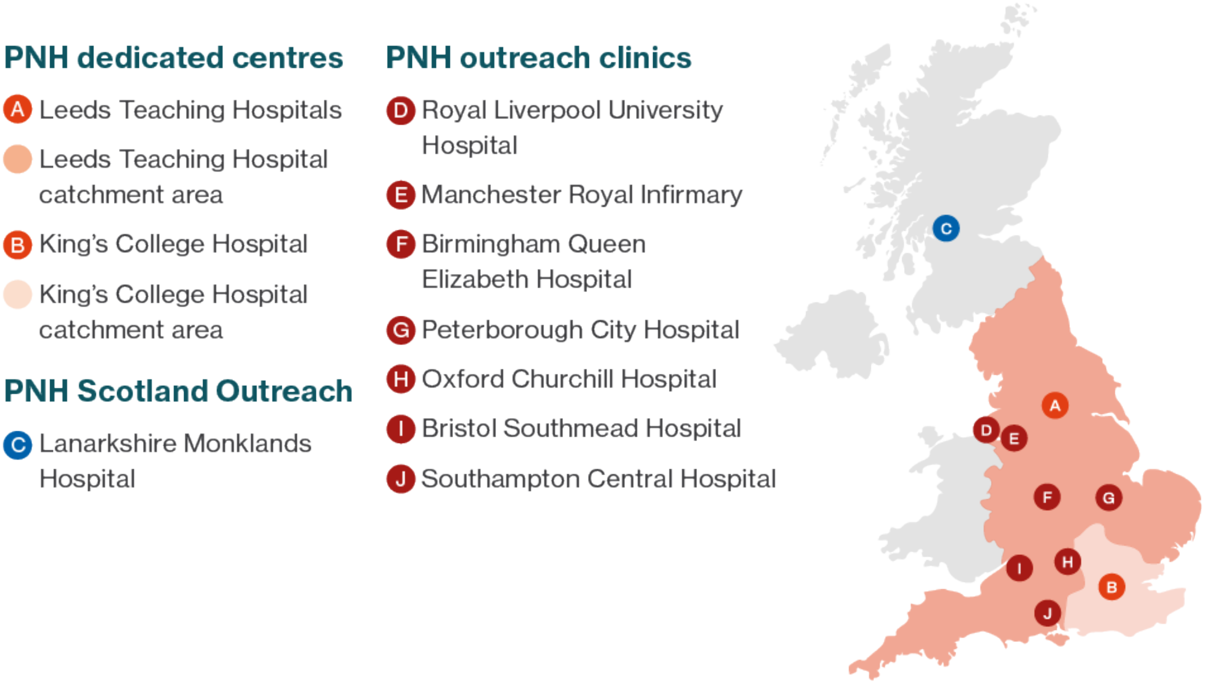

If you have PNH cells detected in your blood, you should be referred to the PNH Service. Your treatment team will manage the referral process and your care will then be a collaboration between the service and your local haematologist.

For more information, visit: https://pnhserviceuk.co.uk/

Starter kit and mini self-care guides

Here you’ll find downloadable resources that can help you in your first steps when you begin treatment with FABHALTA®▼ (iptacopan).

You can also access a selection of planning tools that can help you with the ongoing management of your PNH. The Treatment diary, Goal setting planner, Staying on track stickers and Appointment planner can help you keep track of your treatment, your symptoms, and your appointments with your healthcare team. It’s also a way to plan in advance what questions you’d like to ask during your appointments.

In addition to the resources on this website, you can find further information and help through our **Connected – Stronger Together Support Programme** – reach out to get guidance on any queries you may have.

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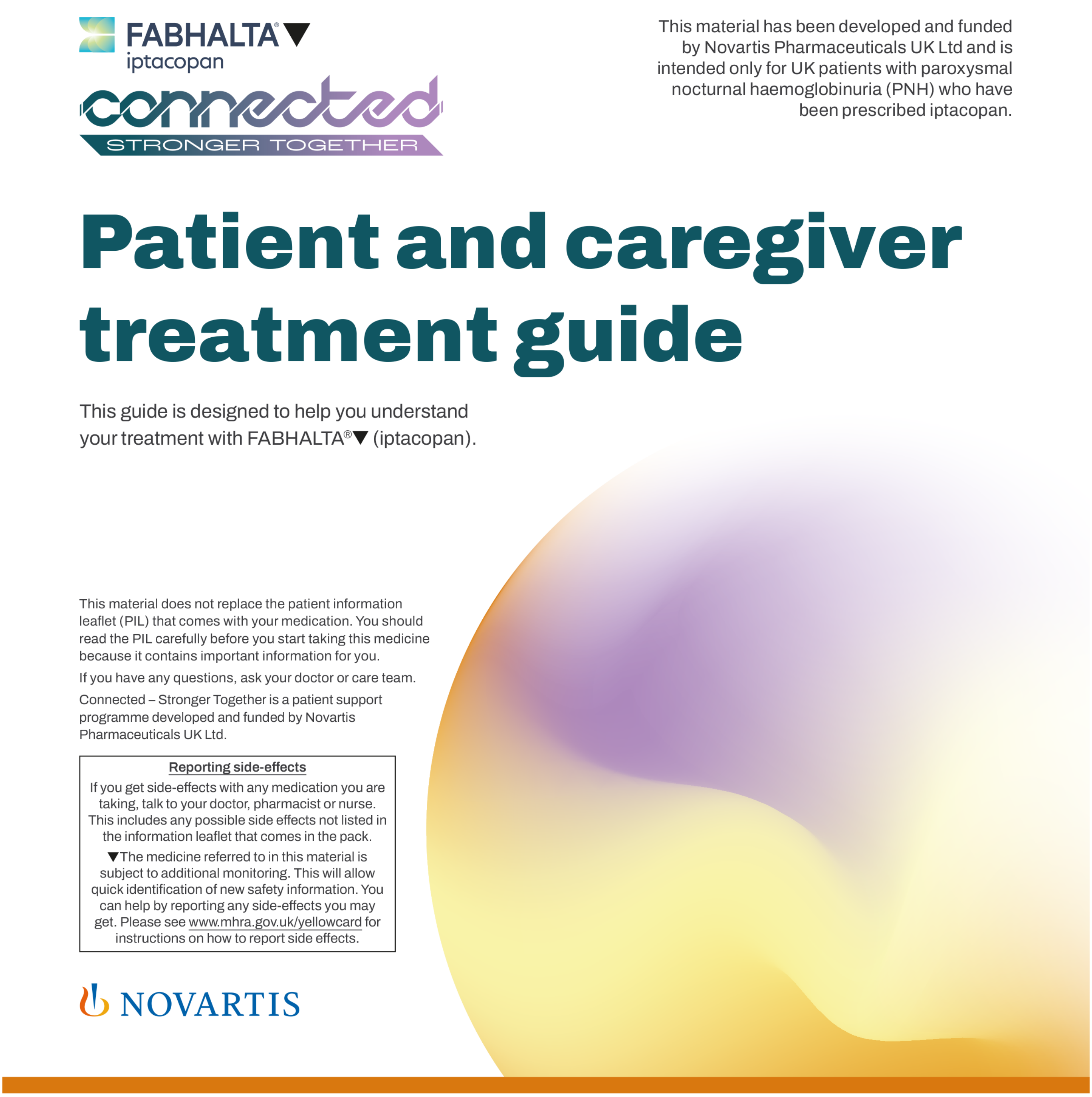

FABHALTA®▼
iptacopan

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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.

Patient and caregiver treatment guide

This guide is designed to help you understand your treatment with FABHALTA®▼ (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.

If you have any questions, ask your doctor or care team.

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Reporting side-effects

If you get side-effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the pack.

▼The medicine referred to in this material is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side-effects you may get. Please see www.mhra.gov.uk/yellowcard for instructions on how to report side effects.

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Patient and caregiver treatment guide

PDF
Download

Your complete guide to iptacopan. What it does, how it's used, possible side effects and practical tips for a smooth treatment experience.

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Treatment diary

This diary is designed to help you monitor your experience with FABHALTA®▼ (iptacopan) and manage your paroxysmal nocturnal haemoglobinuria (PNH).

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Treatment diary

PDF
Download

A diary to help you keep track of your appointments, treatments, test results, symptoms, side effects or changes in well-being. This can aid discussions with your healthcare team about your treatment.

Image

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Goal setting planner

This planner is designed to help you set meaningful goals to support you to stay on track with your treatment with FABHALTA®▼ (iptacopan).

Goal setting planner

PDF
Download

Simple motivational guidance on how to set meaningful personal and treatment-related goals.

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Your appointment planner

As you begin treatment with FABHALTA® ▼ (iptacopan), you will likely have lots of questions about life with paroxysmal nocturnal haemoglobinuria (PNH) and your treatment. Planning and preparing for your appointments with your healthcare team is a good way to ensure all of your questions are answered.

How to use this guide

This guide is designed to support your discussions with your healthcare team. You can also use the treatment diary included in your starter kit to track your symptoms over time and plan for your appointments.

Reflect on your last month and fill in the different sections of the guide to prepare for your next appointment. Bring your completed guide to your next appointment and discuss it with a member of your care team.

Today's date:

Record today's date so you can monitor and reflect on how you're feeling over time.

Symptoms

If you have experienced any PNH symptoms lately, rank how each symptom has impacted your daily life.
For further information on symptoms and side effects, please refer to the treatment guide included in your starter kit.

1 = hasn't impacted my daily life at all; 5 = has had a significant impact on my daily life

Abdominal pain	**Chest pain**	**Breathlessness**	**Yellowing of skin/eyes**
☐1 ☐2 ☐3 ☐4 ☐5	☐1 ☐2 ☐3 ☐4 ☐5	☐1 ☐2 ☐3 ☐4 ☐5	☐1 ☐2 ☐3 ☐4 ☐5
Difficulty swallowing	**Erectile dysfunction**	**Fatigue**	**Dark urine**
☐1 ☐2 ☐3 ☐4 ☐5	☐1 ☐2 ☐3 ☐4 ☐5	☐1 ☐2 ☐3 ☐4 ☐5	☐1 ☐2 ☐3 ☐4 ☐5

Others:

Emotions

How is your PNH affecting you emotionally? Use this box to describe how you have been feeling recently.
You can include any worries or fears you have, as well as any positive feelings you've had.

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Appointment planner

PDF
Download

A checklist of suggested questions to ask your healthcare team, to make the most of your appointments and treatment.

Glossary

The following are common terms used when discussing PNH and iptacopan. Knowing these terms will help you understand your condition and its treatment.

Anaemia
A low level of healthy red blood cells in the blood.

Clinical trial
A test on a drug to find out if it is effective and safe in people with a specific health condition.

Complement inhibitors
Medicines that reduce the activity of the complement system, a part of the immune system.

Complement system
A part of the immune system that helps fight infection and removes damaged blood cells.

Endpoint
A clinical endpoint is an outcome that shows the direct benefit of a drug.

Factor B
A protein that increases the activity of the complement system.

Fatigue
Extreme, persistent exhaustion that does not improve or hardly improves, despite supposedly sufficient rest or sleep.

Gene
A unit of biological material carrying information that determines what features and characteristics are passed on to you.

Haemoglobin
A protein in red blood cells that transports oxygen around the body.

Haemolysis
Breakdown of red blood cells.

Meningitis
A serious infection of the protective membranes that surround the brain and spinal cord (meninges), that causes a stiff neck, headache and fever.

Mutation

A change to one or more genes.

National PNH Service
The National PNH Service cares for and supports patients with PNH throughout the UK. The service is funded by NHS England as a Highly Specialised Service.

Paroxysmal
Happens suddenly, occurs over and over again.

Paroxysmal nocturnal haemoglobinuria (PNH)
A rare and serious blood disorder in which red blood cells break apart more easily, leading to anaemia and other complications.

Platelet
Cell fragment, found in large numbers in blood and involved in clotting.

Pneumonia
A serious infection of one or both of the lungs.

Proteins
Large molecules that have various roles in the body, including building and repairing different types of cells and chemicals involved in biological processes.

Red blood cells
Blood cells that carry oxygen from the lungs to the rest of the body.

Frequently asked questions

The information on this website does not replace your patient information leaflet. Please always refer to your patient information leaflet for more information.

What is FABHALTA®?

FABHALTA®, also known as iptacopan, is a medication used on its own to treat PNH in adults who have anaemia (low levels of red blood cells due to the breakdown of their red blood cells). The active substance in the medicine targets a protein called Factor B, which is involved in a part of the body’s immune system called the ‘complement system’.[1]

How does iptacopan work?

Iptacopan works by blocking the Factor B protein of the complement system, a part of your immune system. This, in turn, stops the activation of the complement system, and reduces the breakdown of red blood cells (haemolysis). This medicine has been shown to increase the number of red blood cells and thus may improve symptoms of anaemia.[1,2]

How is it taken?

The recommended dose for iptacopan is one 200 mg capsule taken twice a day by mouth with a glass of water, once in the morning and once in the evening. Iptacopan can be taken with or without food.[1]

It’s important to take your medication as prescribed by your healthcare team so that it can work continuously to reduce the risk of haemolysis.[1]

Do I need to take tests when I have my iptacopan treatment?

Your healthcare team will regularly monitor your condition to check that the treatment is having the desired effect. This includes measuring your lactate dehydrogenase levels (also known as LDH) to check for any signs of the breakdown of red blood cells.[3]

How long will I need to take my medication?

PNH is a lifelong condition and it’s expected that you’ll need to take your treatment for a long time. Your healthcare team will regularly monitor your condition to check that the treatment is having the desired effect. If you have questions about how long you’ll need to take iptacopan, talk to your healthcare team.[1]

Why do I need to get vaccinated?

Iptacopan may increase your risk of infection caused by bacteria. Talk to your healthcare team to understand more about vaccinations if you have questions.[1]

Do not take iptacopan if you have not been vaccinated against *Neisseria meningitidis* and *Streptococcus pneumoniae*, unless your doctor decides that urgent treatment with iptacopan is needed. Please refer to your patient information leaflet for more information.[1]

What should I do if I miss a dose?

If you miss a dose or doses, it’s important that you take one dose of iptacopan as soon as possible, even if it’s shortly before your next dose is due. You can then carry on as normal with your regular dosing schedule. If you miss several doses in a row, contact your healthcare team, who may decide to monitor you for any signs of the breakdown of red blood cells.[1]

I’m going on holiday soon. Can I get extra medication so that I don’t run out?

If you’re planning any change from your routine, such as a holiday or time away from home, it’s important to make sure you don’t run out of your prescribed treatment during that time. You can speak to your healthcare team/pharmacist in advance if you need to change the number of capsules for your next prescription.

What should I do if I take too much of my medication?

If you’ve accidentally taken too many capsules or if someone else accidentally takes your medicine, talk to your healthcare team immediately.[1]

What should I do if I get side effects from my treatment?

Whilst no one wants to have unwanted side effects from their treatment, just remember that it isn’t unusual to experience them. What’s most important is that you speak to your healthcare team immediately so that they can advise you on how to proceed.[1]

Should I stop taking my treatment if I experience side effects?

Stopping your treatment with iptacopan can make your condition worse. Do not stop taking iptacopan without talking to your healthcare team first. If your healthcare team decides to stop your treatment, you'll be monitored closely for at least 2 weeks after stopping treatment for any signs of the breakdown of red blood cells (haemolysis). Your healthcare team may prescribe a different PNH medicine or have you restart iptacopan treatment.[1]

Symptoms or problems that can happen due to breakdown of red blood cells include: low levels of haemoglobin in your blood, tiredness, blood in the urine, pain in the stomach (abdomen), shortness of breath, trouble swallowing, erectile dysfunction (impotence), and blood clots (thrombosis).

If you experience any of these after stopping treatment, contact your doctor.

Can I take iptacopan if I'm pregnant?

If you’re pregnant or breastfeeding, or think you may be pregnant or are planning to have a baby, ask your healthcare team for advice before taking iptacopan. You should also tell your healthcare team if you become pregnant during treatment with iptacopan. They will discuss with you the potential risks of taking it during pregnancy or breastfeeding.[1]

Your doctor will decide whether you should take iptacopan while you are pregnant only after a careful risk–benefit assessment. It is unknown whether iptacopan passes into human milk and may affect the breast-fed newborn/infant.[1]

Your doctor will decide whether you should stop breastfeeding or stop iptacopan treatment, taking into account the benefit of breastfeeding for your baby and the benefit of treatment for you.[1]

If you experience any symptoms or problems during or after stopping your treatment, please contact your healthcare team.[1]

References

1. FABHALTA® Patient information leaflet.

2. Risitano AM, et al. EHA 2023, 8–11 June; Frankfurt, Germany. Oral S182.

3. FABHALTA® Summary of Product Characteristics.

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By reporting side-effects you can help provide more information on the safety of your medication.

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