

Vaccination Guide

This guide is designed to provide details on the importance of vaccinations and why you'll need them before starting your treatment with FABHALTA®.

Get the support you need with



replenishEd
pnh education & support

As a patient starting treatment with Fabhalta® (iptacopan) you are invited to enrol in the **replenishEd patient support program**.

By joining **replenishEd** you will have the option to receive:

-  Educational emails on managing PNH with oral therapy
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Please scan the QR code to enrol in the replenishEd patient support program, or go to:
www.replenished-pnh.com.au

Trouble signing up? Call 1800 290 652
or email support@replenished-pnh.com.au

▼ There is additional monitoring in place for FABHALTA® (iptacopan) to help quickly identify new side effects. If you experience any side effects, talk to your doctor, nurse or pharmacist/other healthcare professional. This includes any possible side effects not listed in this guide. If you have any questions or concerns about FABHALTA®, speak with a healthcare professional.



Getting ready to start FABHALTA®

Getting vaccinated is the first key step in your journey with FABHALTA®. We know you may have many questions and we're here to support you along the way.

Within this guide you will find lots of useful information to help you understand:

- What vaccines you need before starting FABHALTA®
- Why vaccines are important
- How to manage vaccine side effects
- How to get your vaccinations

Let's get started with FABHALTA®

Please read this guide carefully. If you have any questions or concerns, you should contact your healthcare team.

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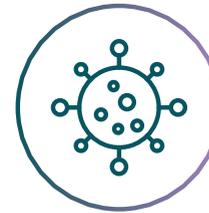
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Why do I need vaccinations before starting FABHALTA®?

The way that FABHALTA® works to treat your condition leads to an increased risk of infection from specific types of bacteria called **encapsulated bacteria**. This is because FABHALTA® disrupts part of the body's natural defences against infection caused by this type of bacteria.



Vaccination before starting treatment with FABHALTA® is the **best way to protect you** against serious diseases such as **meningitis**, **pneumonia** and **sepsis**. Multiple vaccinations may be needed to give you the protection you need.



The vaccines you may be given are:

- Meningococcal vaccine (two types, called MenACWY and MenB)
- Pneumococcal vaccine
- Haemophilus influenzae type B (Hib) vaccine

Don't worry, your healthcare team will inform you which vaccinations you need before starting treatment with FABHALTA®.

When do I need to have my vaccinations?

You will need to have had the first dose of all the required vaccinations at least 2 weeks before starting treatment with FABHALTA®. If you are switching from another paroxysmal nocturnal haemoglobinuria (PNH) treatment, you may have already been vaccinated against meningitis.

Your healthcare team will also make sure that you are revaccinated when needed to help prevent serious infections. Although the vaccinations you will receive are effective at reducing the chances of serious infection, they may not prevent them entirely. Please refer to page 8 to learn more about the **possible signs of infection**.

Below is an example timeline of when you will need to have your vaccinations before starting FABHALTA®.

Example Vaccination timeline (no prior vaccinations)



It's important that you keep track of your vaccinations. You can use the vaccination tracker on page 16 of this guide to help you to keep an up-to-date record of when you receive your vaccinations. Please share this information with your healthcare team.

You may need to take antibiotics too – **learn more about this on page 11**

What if I've already had these vaccinations?

Even if you've already had some of these vaccinations in the past, your healthcare team will want to make sure you are up to date. All the vaccines you will need have been proven to be well tolerated. Receiving an extra dose has not been shown to be harmful or cause side effects in most cases.

Maybe you're all up to date with your vaccinations. Don't worry, your healthcare team will inform you if you need to repeat them or require additional vaccinations before starting treatment with FABHALTA®.



What are the possible signs of infection?

Although the risk is small, serious bacterial infections may quickly become life threatening if they're not identified and treated early.

Here are a few signs and symptoms of serious infection you should look out for:



Fever with or without...

shivers or chills, chest pain and cough, breathlessness/fast breathing, high heart rate, rash, headache



Headache with...

nausea (feeling sick) or vomiting, stiff neck or stiff back



Feelings of...

confusion, dizziness



Discomfort...

body aches with flu-like symptoms, clammy skin, eyes being sensitive to light

You must contact your healthcare team immediately if you experience any of these symptoms.



Your patient safety card also lists the signs of serious infection



When you are first prescribed FABHALTA®, you will be given a **patient safety card**.

This card contains important safety information about the risk of infection while taking FABHALTA® and what to do if you experience certain signs or symptoms.

If you have not received a patient safety card, please contact your healthcare team.

Practical guidance

What if I have to start treatment immediately?



If you have to start treatment immediately, your healthcare team can prescribe you antibiotics until 2 weeks after vaccination, which will reduce the possibility of a bacterial infection. FABHALTA® will only be prescribed to you once your healthcare team confirms that you have received the required vaccinations or are receiving antibiotics.

Where can I get vaccinated?



Getting the vaccinations you need will depend on where you live. Your healthcare team will be able to provide you with information about where and how you can access these vaccinations.

Can I have all the vaccines at the same time?



Some vaccines can be given at the same time; however, the two types of meningococcal vaccines must be given separately. If you need to have the different vaccinations at the same time, your healthcare team will make sure to inject each vaccine into a different part of your body.

You will need to have two shots of the MenACWY vaccine at least 8 weeks apart, and two shots of the MenB vaccine at least 4 weeks apart. You will already be sufficiently protected against meningococcal infections after the first dose to start FABHALTA®.

Do I really need to have these vaccines?

Vaccines are considered one of the most important advances in modern medicine. They have saved millions of lives around the world by reducing or even eliminating many serious infectious diseases.

Studies have shown a global reduction in infections and deaths from meningitis after the meningitis vaccines were introduced to routine vaccination schedules or as part of a mass campaign. The use of the Hib vaccine (one of the vaccinations you may be recommended to receive) has led to dramatic declines of >90% in invasive Hib disease in the countries that have included these vaccines in national immunisation programmes.

Although vaccines are proven to be effective and safe, some people don't get all the vaccines that are freely available to them. This is known as vaccine hesitancy. It was listed by the World Health Organization (WHO) as one of the most pressing threats to global health in 2019.

Vaccination success

One of the biggest success stories of vaccination is the smallpox vaccine. Its use has been so effective that smallpox no longer exists today!



Trusting online sources of information about vaccinations

Nowadays, it's easy for misinformation to spread online and sometimes it can be hard to know where to turn or who to ask for factual information.

Here are a few suggestions to help you validate information you find on vaccines:

Where is it from?



Reliable information will always have a clear source. Copy and pasted content, without a source, may not necessarily be reliable or true. You can check the section of the information online to see if you can find an original source.

Are you missing the whole story?



Trustworthy information will contain all the information, not simply a catchy or misleading headline. If a piece of information is missing context, proceed with caution before trusting it completely. You can also search online to find out more information on the subject matter.

How does it make you feel?



Misinformation is designed to be shared and we are more likely to share something when we have an emotional connection to it. People that create misinformation often use our everyday hopes and fears to drive clicks and engagement.

Tracking your vaccinations

It's important that you keep track of your vaccinations. You can use this vaccination tracker to help you keep an up-to-date record of when you receive your vaccinations. Please share this information with your healthcare team.

Tracking your vaccinations is simple. Pull out this page and turn over to see your tracker.



Vaccination tracker

Target FABHALTA® treatment start date:

You must have had the first dose of all the required vaccinations at least 2 weeks before starting treatment. Your healthcare team will advise you on timings.

The four required and recommended vaccines:

Meningococcal		Pneumococcal	Hib
MenACWY	MenB	Type	Past vaccination (Dates received)
Past vaccination (Dates received)	Past vaccination (Dates received)
.....	Past vaccination (Dates received)	Vaccination schedule (If vaccination needed)
Vaccination schedule (If vaccination needed)	Vaccination schedule (If vaccination needed)	Dose
Dose 1	Dose 1	Vaccination schedule (If vaccination needed)
Dose 2	Dose 2	Dose
Booster	Booster	

Tracking ongoing vaccinations: Work with your healthcare team to determine whether you require revaccinations to prevent serious infections.

Recommended revaccination schedule	Recommended revaccination schedule	Recommended revaccination schedule
.....
Record of doses	Record of doses	Record of doses
.....



Summary of pretreatment vaccinations

How do these vaccines work?

These vaccines contain the weakened or inactive parts of a virus (antigen) that triggers an immune response in your body. You won't get the disease from the vaccine, but your immune system will learn to recognise and fight the bug if you come into contact with it.

When will I need my vaccine?

Meningococcal vaccines: MenACWY: two shots at least 8 weeks apart, first dose 4 weeks before starting treatment. **MenB:** two shots at least 4 weeks apart, first dose at least 2 weeks before starting treatment. **Pneumococcal and Hib vaccines:** At least 2 weeks before starting treatment.

Will I experience any side effects from the vaccine?

Side effects can happen, but not all patients will experience these symptoms.

Meningococcal vaccines: Redness, hardening and itching at the injection site, high temperature (above 38°C), headache, feeling sick and tiredness.

Pneumococcal vaccine: Pain, redness and swelling at the injection site, limited movement of the injected arm, tiredness, headache, chills, decreased appetite, muscle and joint pain.

Hib vaccine: Pain, redness or swelling at the injection site, high temperature, irritability, loss of appetite and sleepiness.

How do I manage vaccine side effects?

You can use paracetamol after vaccination to reduce the risk of a fever on your healthcare team's advice.

Common terms to know

Haemophilus influenzae type b (Hib)

A bacterium that can cause a number of life-threatening illnesses including meningitis, septicaemia and pneumonia. Babies and young children are most at risk.

Meningitis

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

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.

Pneumonia

A serious infection of one or both lungs.

Vaccine

A product often made from extracts of killed viruses or bacteria, or from live, weakened strains of viruses or bacteria. A vaccine can stimulate an immune response that protects against natural infection.

Find the support you need

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Please scan here to visit our patient website to find more information, and to access electronic copies of your Fabhalta® onboarding materials

This material has been produced by Novartis Pharma AG. This material is intended only for patients with paroxysmal nocturnal haemoglobinuria (PNH) who have been prescribed FABHALTA®. This is provided for information/educational purposes only and is not intended to replace discussions with your doctor or care team.

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