

# Patient/Caregiver Guide to treatment with **FABHALTA®▼ (iptacopan)**

This guide was developed by Novartis Ireland Ltd to fulfil the conditions of the marketing authorisation and has been approved by the HPRA. This guide provides important safety information for patients/caregivers about treatment with iptacopan.

**This guide is not a replacement for 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.**

▼ 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](http://www.hpra.ie). Side effects can also be reported to Novartis preferably at [www.novartis.com/report](http://www.novartis.com/report), by emailing [drugsafety.dublin@novartis.com](mailto:drugsafety.dublin@novartis.com) or by calling (01) 2080 612.

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

## Introduction

patients/caregivers with important information about:

- the risk of serious infection caused by bacteria during treatment with ipilimumab

## prevent infections

- the risk of serious breakdown of red blood cells (haemolysis) if treatment with iptacopan is stopped
- reporting any side effects you experience with iptacopan
- enrolling in the post-authorisation safety study (PASS) 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...

Prescribing doctor: .....  
Nurse: .....  
Pharmacist: .....

**Other HCP:** .....

# Your patient safety card

If you are not prescribed a prescription, you will be given a patient safety card.

information about the risk of infection while taking intacopan, and what to do if you get certain signs

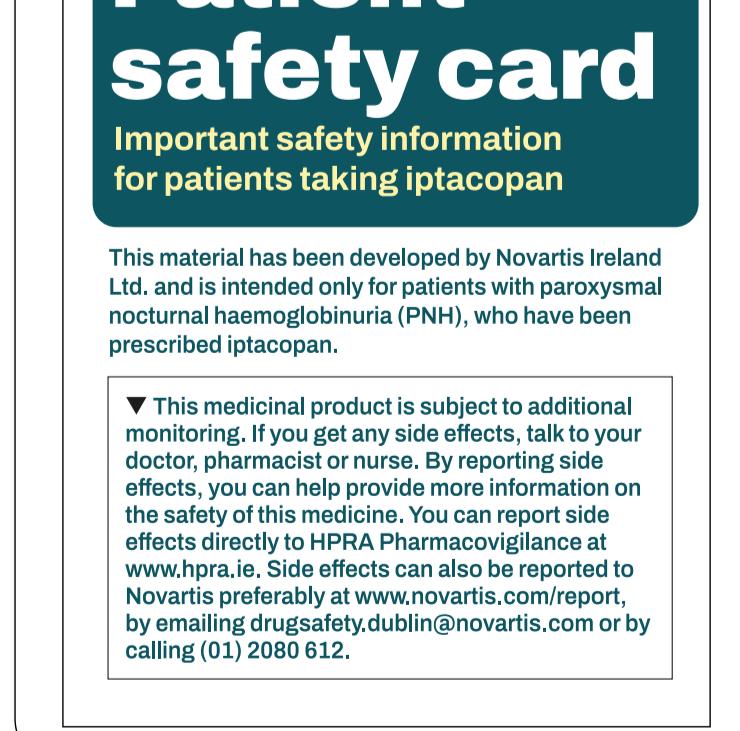
Keep this card with you at

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 if you need medical help.

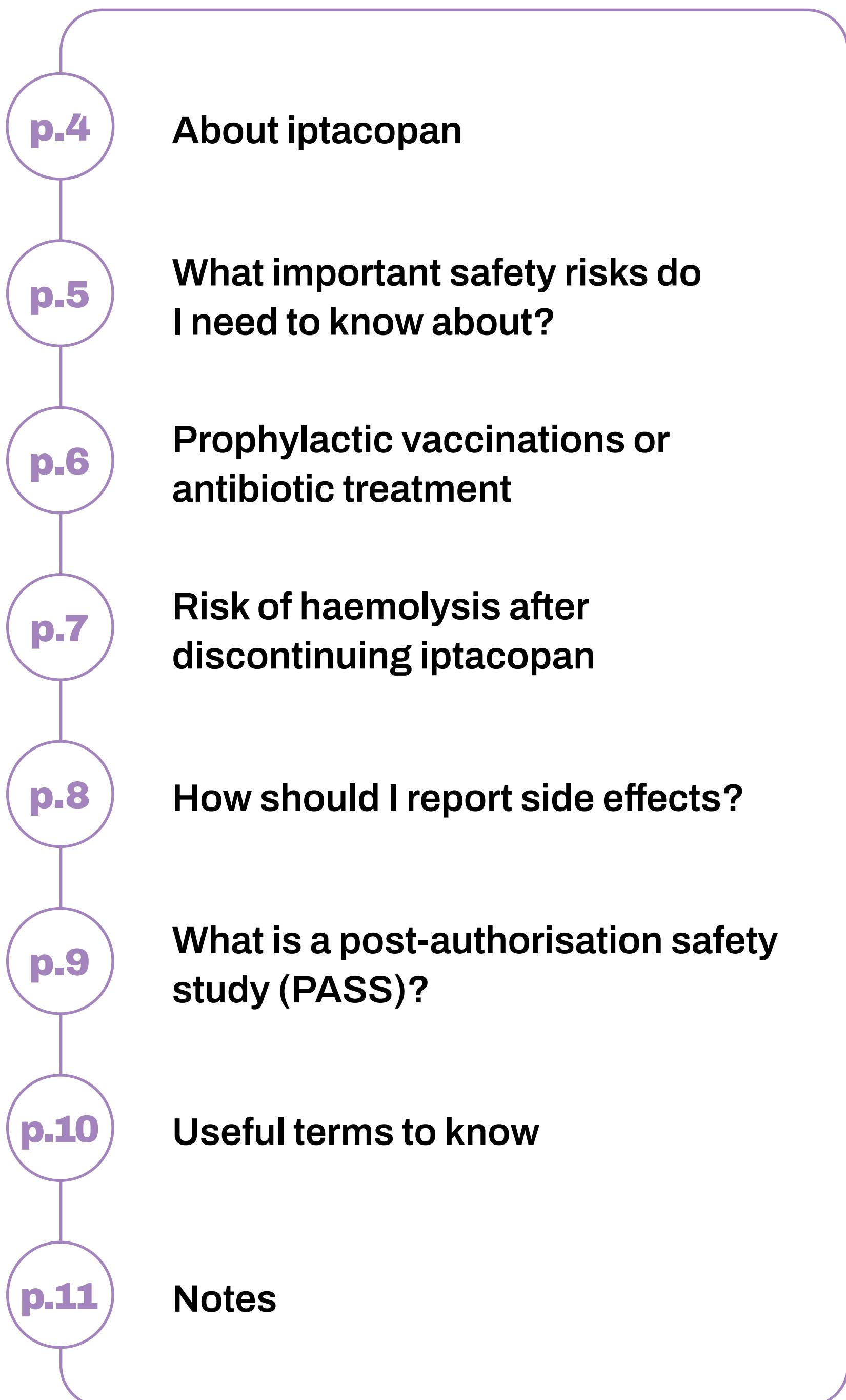
that you are being treated with iptacopan. This will help them to diagnose and treat you correctly.

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

The logo for FABHALTA intaconan is enclosed in a rounded rectangular frame. It features a stylized leaf icon composed of three curved lines to the left of the brand name 'FABHALTA' in a bold, sans-serif font. A registered trademark symbol (®) is positioned above the letter 'A', and a downward-pointing triangle is to the right of the 'TA'. Below the main name, the word 'intaconan' is written in a smaller, lowercase, sans-serif font.



# What is in this guide?



# About iptacopan



## **What is iptacopan?<sup>1</sup>**

Iptacopan is used on its own in adults to treat paroxysmal nocturnal haemoglobinuria (PNH) with anaemia (low levels of red blood cells) due to the breakdown of red blood cells.

# What important safety risks do I need to know about?<sup>1</sup>

## Risk of serious 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* (bacteria that cause meningococcal disease, including serious infection of the linings of the brain and of the blood), *Streptococcus pneumoniae* (bacteria causing pneumococcal disease, including infection of the lungs, ears and blood) and *Haemophilus influenzae* Type B (Hib; a type of bacteria that cause serious infection in the lungs, blood or brain).

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
  - 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

**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 patient safety card with you and show it to any healthcare professional involved in your care to let them know you are being treated with iptacopan.**

# Vaccinations and/or antibiotics to prevent infections<sup>1</sup>



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 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 re-vaccinated as needed.

Please be aware, vaccinations reduce the chances of developing serious infections, but do not prevent them entirely.

# Risk of haemolysis after discontinuing iptacopan

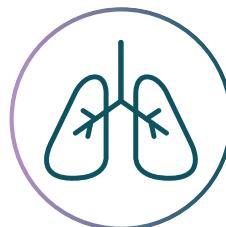
**Discontinuing iptacopan may increase the risk of serious breakdown of red blood cells (haemolysis). It is important that you adhere to your prescribed treatment regimen.**

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

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



Low levels of haemoglobin in your blood, as seen in blood tests



Shortness of breath



Tiredness



Trouble swallowing



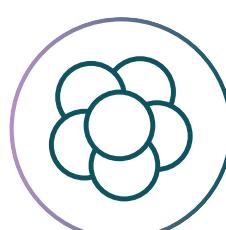
Blood in the urine



Erectile dysfunction (impotence)



Pain in the stomach (abdomen)



Blood clots (thrombosis)

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

# How should I report side effects?

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

If you have any of the side effects listed in the patient information leaflet, or any other side effects, including infections or serious haemolysis, report them immediately to a healthcare professional.

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](http://www.hpra.ie). Side effects can also be reported to Novartis preferably at [www.novartis.com/report](http://www.novartis.com/report), by emailing [drugsafety.dublin@novartis.com](mailto:drugsafety.dublin@novartis.com) or by calling (01) 2080 612.

# **What is a postauthorisation 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.

# Useful terms to know

## Anaemia

A low level of red blood cells in the blood. Anaemia is diagnosed by measuring the level of haemoglobin in the blood. Haemoglobin levels over 12 g/dL are considered normal for women, while over 13 g/dL are considered normal for men.

## Complement system

A part of the immune system that helps fight infection and remove damaged cells.

## Haemoglobin

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

## Haemolysis

Destruction 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.

## 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 of the lungs.

## Red blood cells

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

## Sepsis

An infection of the blood that causes the body's immune system to go into overdrive and can be life-threatening.

## Thrombosis

When blood clots form in healthy blood vessels, which can block normal blood flow.

# Notes

Please refer to the patient information leaflet for more information.  
**Patient/Caregiver Guide to treatment with iptacopan**

## Patient/Caregiver Guide to treatment with Iptacopan

## References:

1. *FABHALTA® (iptacopan)* Patient Information Leaflet, available at [www.medicines.ie](http://www.medicines.ie)

This booklet has been produced by Novartis Ireland Ltd.

The information provided is for educational purposes only and is not intended to replace discussions with your doctor or care team.

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