

A guide to treatment with Fabhalta[®]▼ (iptacopan) for C3 glomerulopathy

This guide is only intended for patients who have been prescribed iptacopan for C3 glomerulopathy, and their caregivers. This guide aims to provide you with important safety information for iptacopan.

This material does not replace the package leaflet that comes with your medicine. You should read the package leaflet carefully before you start taking this medicine because it contains important information for you.

Please keep this document for future reference.

▼There is additional monitoring in place for 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 or the leaflet you will find in the package.

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 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.

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

Introduction

This guide has been developed to provide:

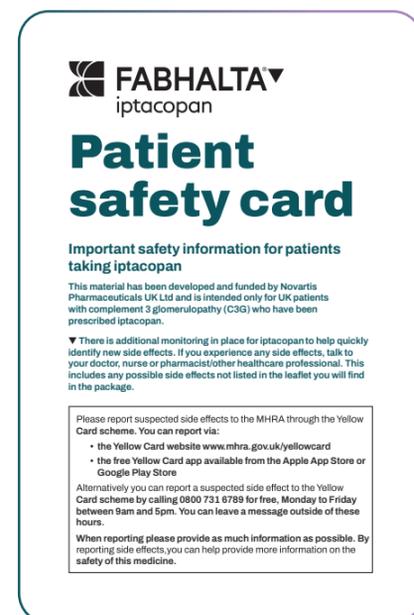
- Information about iptacopan and how it works
- Important safety information for iptacopan

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

Doctor:

Nurse:

Pharmacist:



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 2 weeks after your last 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?

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About iptacopan



What is iptacopan?

Iptacopan is used in adults to treat patients with complement 3 glomerulopathy (C3G) together with a renin–angiotensin-system inhibitor (RAS inhibitor), or alone if a RAS inhibitor does not work well or cannot be used.

Iptacopan belongs to a group of medicines called complement inhibitors, which work by blocking specific parts of the body’s immune system called the “complement system”. The active substance in iptacopan, targets a protein in the complement system called Factor B and this reduces the amount of C3 in the kidneys, helping to stabilise kidney function.



What happens in C3G?

In patients with C3G, the complement system is overactive, leading to deposition of C3 within the glomeruli (a part of the kidneys) causing inflammation and damage. As a result, patients with C3G often have high levels of protein in their urine (proteinuria) and progressive decline in kidney function over time.



How does iptacopan work?

By attaching to and blocking the Factor B protein, iptacopan can reduce deposits of C3 in the kidneys. This helps to reduce levels of protein in the urine and stabilise kidney function.

How do I take iptacopan?

The recommended dose is one capsule (200 mg) twice daily, once in the morning and once in the evening. Swallow the capsule with a glass of water.

Iptacopan can be taken with or without food.

It is important to not forget any dose. Taking iptacopan at the same time each day will help you remember to take your medicine. Please take iptacopan according to the schedule exactly as your doctor tells you to ensure continuous treatment of C3G.

Do not stop taking iptacopan without talking to your doctor first.

What if I forget to take iptacopan?

If you miss a dose or doses, take one dose of iptacopan as soon as you remember (even if it is shortly before the next scheduled dose), then take the next dose at the usual time.

What if I take too much iptacopan?

If you have accidentally taken too many capsules or if someone else accidentally takes your medicine, talk to your doctor or nurse immediately.

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**
 - 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 safety card with you and present it if the healthcare professional contacted is not the one involved in your C3G treatment.

Vaccination or 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 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 do not prevent them entirely.

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 package leaflet, or any other side effects, including infections, report them immediately to a healthcare professional.

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Useful terms to know

Angiotensin-converting enzyme inhibitors (ACEi)

Medicines that help relax the veins and arteries to lower blood pressure.

Angiotensin II receptor blockers (ARBs)

Medicines that help relax the veins and arteries to lower blood pressure.

Complement component 3 (C3)

A blood protein that plays a key role in normal immunity.

Complement 3 glomerulopathy (C3G)

A rare complement-mediated kidney disease in which protein deposits in the kidneys cause damage.

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 remove damaged cells.

Factor B

A protein that increases activity of the complement system.

Immune system

A complex network of organs cells and proteins that defends the body against infection and diseases.

Meningitis

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

Pneumonia

A serious infection of one or both of the lungs.

Protein

Large molecules that have various roles in the body, including building and repairing tissues, enzymes and hormones.

Proteinuria

High levels of protein in urine.

Renin-angiotensin system (RAS) inhibitors

A class of drugs that treat conditions like high blood pressure and heart failure by blocking the actions of RAS, a hormone system that regulates blood pressure and fluid levels in the body.

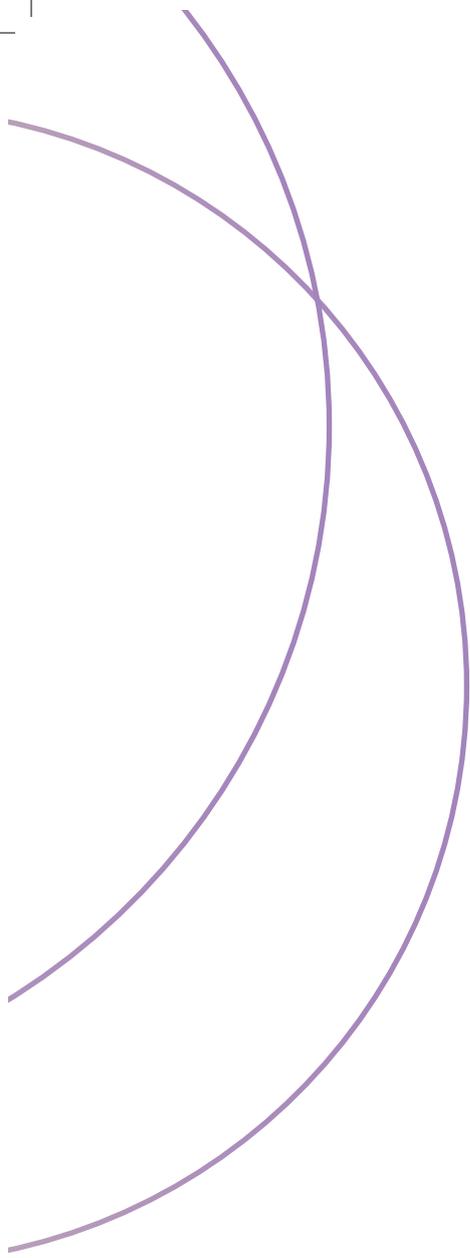
Sepsis

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

Notes



Two columns of horizontal dotted lines for taking notes.



This booklet has been produced and funded by Novartis Pharmaceuticals UK Ltd.
The information provided is for educational purposes only and is not intended to
replace discussions with your treating healthcare team.

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