

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using FABHALTA?

FABHALTA contains the active ingredient iptacopan. FABHALTA is used to treat adult patients with: 1) paroxysmal nocturnal hemoglobinuria (PNH) and 2) complement 3 glomerulopathy (C3G). For more information, see Section [1. Why am I using FABHALTA?](#) in the full CMI.

2. What should I know before I use FABHALTA?

- Do not use if you have ever had an allergic reaction to iptacopan or any of the ingredients listed at the end of the CMI.
- Talk to your doctor about your vaccination history. You may need to receive some vaccinations unless your doctor decides that urgent treatment with FABHALTA is needed.
- If you have a serious bacterial infection prior to starting treatment, do not take FABHALTA and tell your doctor.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use FABHALTA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FABHALTA and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use FABHALTA?

- The recommended dose is 200 mg twice daily, once in the morning and once in the evening.
- Swallow the FABHALTA capsule with a glass of water. FABHALTA can be taken with or without food.

More instructions can be found in Section [4. How do I use FABHALTA?](#) in the full CMI.

5. What should I know while taking FABHALTA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using FABHALTA. • Call your doctor straight away if you experience any signs or symptoms of an infection or signs or symptoms due to breakdown of red blood cells like tiredness, shortness of breath, blood in the urine. • Tell your healthcare provider if you develop any signs or symptoms of an infection.
Things you should not do	• Do not stop taking this medicine suddenly without talking to your doctor first.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how FABHALTA affects you
Drinking alcohol	• There are no known interactions between FABHALTA and alcohol.
Looking after your medicine	• Store below 30°C.

For more information, see Section [5. What should I know while using FABHALTA?](#) in the full CMI.

6. Are there any side effects?

Common and very common side effects include headache, dizziness, diarrhoea, joint and stomach pain, feeling sick, and common colds. Inform your doctor straight away if you experience sudden bleeding or bruising which may be caused by fewer platelets in the blood, and symptoms of serious infections such as fevers or if you experience a persistent cough or irritation of the airways. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

As FABHALTA blocks a part of your immune system it increases the risk of severe infections or sepsis caused by certain bacteria, such as *Streptococcus pneumoniae*, that can cause pneumonia; *Haemophilus influenzae* type B that can cause Hib infections; and *Neisseria meningitidis*, which can cause meningitis or a severe infection of the blood.

These infections require urgent and appropriate care as they can become rapidly fatal or life-threatening or lead to major disabilities. It is important to understand the precautions to take to reduce the risk of these infections and what to do if you are worried you may have an infection (see section 2. What should I know before I start using FABHALTA and section 6. Are there any side effects or refer to your Patient Card).

- You must be vaccinated against *Streptococcus pneumoniae* and *Neisseria meningitidis* before starting FABHALTA. It is recommended to vaccinate against *Haemophilus influenzae* type B.
- If you start treatment with FABHALTA less than 2 weeks after receiving any of the vaccines, you must also take antibiotics until 2 weeks after you have been vaccinated to reduce the risk of infection.
- You will need to be aware of the symptoms of these infections (see section 2. What should I know before I start using FABHALTA and section 6. Are there any side effects or refer to your Patient Card) and notify your doctor immediately if any of the symptoms occur.
- If you cannot reach your doctor, go to the emergency department at the nearest hospital. Show your Patient Card to any doctor or nurse who treats you.

FABHALTA®

Active ingredient: *iptacopan*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FABHALTA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FABHALTA.**

Where to find information in this leaflet:

1. [Why am I using FABHALTA?](#)
2. [What should I know before I take FABHALTA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take FABHALTA?](#)
5. [What should I know while taking FABHALTA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using FABHALTA?

FABHALTA contains the active ingredient **iptacopan**.

FABHALTA is designed to target the Factor B protein which is part of the body's defence system called the 'complement system'. In patients with PNH, FABHALTA prevents your body's immune system from breaking down red blood cells. In patients with C3G, FABHALTA prevents your body's immune system from depositing a type of protein in the kidneys.

FABHALTA is used to treat adult patients with a blood disorder called paroxysmal nocturnal hemoglobinuria (PNH)

In patients with PNH, the complement system is overactive and attacks the red blood cells which can lead to low blood counts (anaemia), tiredness, difficulty in functioning, pain, pain in the stomach (abdomen), dark urine, shortness of breath, difficulty swallowing, erectile dysfunction, and blood clots. By attaching to the Factor B protein, FABHALTA blocks the complement system from attacking the red blood cells and so controls the symptoms of the disease. This medicine has been shown to increase the number of red blood cells (reduce anaemia) and control PNH.

FABHALTA is also used to treat adult patients with a kidney disease called complement 3 glomerulopathy (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 fibrosis. As a result, patients with C3G often have high levels of protein in their urine (proteinuria) and a progressive decline in kidney function over time. By attaching to the Factor B protein, iptacopan can reduce the deposition of C3 in the kidneys. This medicine has been shown to reduce levels of protein in the urine and the decline in kidney function.

If you have any questions about how FABHALTA works or why this medicine has been prescribed for you, ask your doctor, pharmacist or healthcare provider.

2. What should I know before I take FABHALTA?

Warnings

Do not use FABHALTA if:

- you are not vaccinated against *Neisseria meningitidis*, *Streptococcus pneumoniae* unless your doctor decides that urgent treatment with FABHALTA is needed.
- you are allergic to iptacopan, or any of the ingredients listed at the end of this leaflet. If you think you may be allergic, ask your doctor for advice.
- you are currently using another complement inhibitor medicine to treat PNH, unless advised by your doctor.

If any of these apply to you, do not take FABHALTA and tell your doctor.

Do not start FABHALTA treatment if:

- you have or recently have had a serious infection caused by encapsulated bacteria. These are severe infections affecting the upper respiratory tract - your nose, throat, lungs, or the linings of the brain and can spread throughout the blood and body. Symptoms include persistent fever, persistent cough or coughing up blood or pus, difficulty in breathing, severe headache or neck stiffness.

Serious infection caused by encapsulated bacteria

- FABHALTA may increase your risk of infections caused by encapsulated bacteria, including *Neisseria meningitidis*, *Streptococcus pneumoniae* and *Haemophilus influenzae* type B.
- Talk to your doctor before you start FABHALTA to be sure that you are vaccinated against *Neisseria meningitidis* and *Streptococcus pneumoniae*. You should also be vaccinated against *Haemophilus influenzae* type B. Even if you have had these vaccinations in the past, you might still need a booster before starting this medicine.
- These vaccinations should be given at least 2 weeks before starting FABHALTA. If this is not possible, you will be vaccinated as soon as possible after you start FABHALTA and your doctor will prescribe antibiotics for you to use until 2 weeks after you have been vaccinated to reduce the risk of infection. Vaccination reduces the risk of serious infections but may not prevent all serious infections. You should be closely monitored by your doctor for symptoms of infection.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Notify your doctor or go to the closest emergency department straight away if you develop symptoms of serious infections, such as fevers. See Section 6 for other symptoms of serious infections.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. You should also tell your doctor if you become pregnant during the treatment with FABHALTA.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss with you the potential risks of taking FABHALTA during pregnancy or breastfeeding.

Children and adolescents

Do not give FABHALTA to children or adolescents below 18 years of age. No data are available on the safety and effectiveness of FABHALTA in this age group.

Older people (65 years of age or above)

You can use FABHALTA if you are aged 65 years or over at the same dose as for other adults. Check with your doctor if you are not sure.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

FABHALTA is not expected to interact with most medicines. However, some medicines may affect how FABHALTA works, or FABHALTA may affect how they work. These include:

- Medicines that strongly affect certain enzymes or transporters, such as rifampicin (used to treat tuberculosis).
- Medicines that are processed by the liver or transported in the body, such as:
 - CYP3A4 substrates (e.g., carbamazepine, ciclosporin, fentanyl, tacrolimus).
 - CYP2C8 substrates (e.g., repaglinide, paclitaxel).
- Medicines with a narrow therapeutic index (where small changes in blood levels can cause harm).

What you need to know:

- Taking FABHALTA with strong inducers of certain enzymes or transporters (such as rifampicin) may reduce the effectiveness of iptacopan. **Do not take these medicines with FABHALTA unless advised by your doctor.**
- FABHALTA may increase the level of some medicines (e.g., repaglinide, paclitaxel) or decrease the level of others (e.g., medicines processed by CYP3A4).
- If you need to take FABHALTA with any of these medicines, your doctor may need to monitor you closely or adjust your dose.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

4. How do I take FABHALTA?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not take more than the prescribed dose.

At least 2 weeks before you start treatment with this medicine, your doctor will review your medical records and may give you one or more vaccinations against certain bacterial infections (see section 2). If you cannot be vaccinated at least 2 weeks before you start treatment with FABHALTA, your doctor will prescribe antibiotics for you to use until 2 weeks after you have been vaccinated, to reduce the risk of infection.

How much to take

- The usual dose is 200 mg twice daily. Swallow the FABHALTA capsule with a glass of water.

When to take FABHALTA

- Take FABHALTA once in the morning and once in the evening. Taking your medicine at the same time each day will help you to remember when to take your medicine.
- FABHALTA can be taken with or without food.
- If you have questions about how long you will need to take FABHALTA, talk to your doctor. PNH is a life-long condition and so it is expected that you will use this medicine for a long-time.

Switching from other paroxysmal nocturnal hemoglobinuria (PNH) medicines to FABHALTA

- If you are switching from a medicine called eculizumab, you should start taking FABHALTA no later than one week after the last dose of eculizumab.
- If you are switching from a medicine called ravulizumab, you should start taking FABHALTA no later than 6 weeks after the last dose of ravulizumab.
- If you are switching from any other PNH medicine, ask your doctor when to start taking FABHALTA.

If you forget to take FABHALTA

If you miss your dose at the usual time, take one dose of FABHALTA as soon as you remember (even if it is soon before the next scheduled dose), then take the next dose at the usual time.

If you use too much FABHALTA

If you think that you have used too much FABHALTA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking FABHALTA?

Things you should do

- Keep all doctor's appointments, as your doctor needs to regularly monitor your condition.
- Your doctor will regularly monitor your condition to check that the treatment is having the desired effect. PNH and C3G are a lifelong conditions, and it is expected that you will need to use FABHALTA for a long time.
- If you have PNH, and your doctor decides to stop your treatment with this medicine, your doctor will monitor you closely for at least 2 weeks after stopping treatment for any signs of the breakdown of red blood cells (haemolysis) due to PNH. Your doctor may prescribe a different PNH medicine or have you restart FABHALTA treatment.

Call your doctor straight away if you experience any of these symptoms of a decrease in haemoglobin level in your blood:

- tiredness
- blood in the urine
- pain in the stomach (abdomen)
- shortness of breath
- blood clots (thrombosis)
- trouble swallowing
- erectile dysfunction (impotence).

Remind any doctor, dentist or pharmacist you visit that you are using FABHALTA.

Things you should not do

- Do not stop taking FABHALTA without talking to your doctor first. PNH and C3G are lifelong conditions, and it is expected that you will need to use FABHALTA for a long time.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FABHALTA affects you.

It is not known if FABHALTA affects a person's ability to drive or use machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

There are no known interactions between FABHALTA and alcohol.

Looking after your medicine

- Store below 30°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date stated on the packaging.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
- Joint pain - Dizziness - Headache - Urinary tract infection - Nausea, feeling sick - Stomach pain - Diarrhoea - Common colds	Speak to your doctor if you have any of these less serious side effects and they don't go away or they worry you.

Serious side effects

Serious side effects	What to do
Infections (symptoms include the following): - Fever with or without shivers or chills - Fever and a rash - Fever with chest pain and cough - Fever with breathlessness/fast breathing - Fever with high heart rate - Headache with nausea/vomiting - Headache with fever - Headache with stiff neck or back - Confusion - Body aches with flu-like symptoms - Clammy skin - Eyes sensitive to light - Persistent cough or irritation of the airways Bleeding-related: - Sudden bleeding or bruising which may be caused by fewer platelets in the blood	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What FABHALTA contains

Active ingredient	iptacopan
Other ingredients (inactive ingredients)	Capsule shell: Gelatin, red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172) Printing ink: Black iron oxide (E172), concentrated ammonia solution (E527), potassium hydroxide (E525), propylene glycol (E1520), shellac (E904)
Potential allergens	sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What FABHALTA looks like

FABHALTA is supplied as hard capsules containing 200 mg iptacopan (as iptacopan hydrochloride monohydrate). The hard capsules are pale yellow, opaque hard capsules, imprinted with "LNP200" on the body and "NVR" on the cap, containing white or almost white to pale purplish-pink powder (AUST R 410830).

FABHALTA is supplied in PVC/PE/PVDC blisters in packs containing 56 hard capsules.

Who distributes FABHALTA

FABHALTA is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited
(ABN 18 004 244 160)

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1 800 671 203

Website: www.novartis.com.au

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