Package leaflet: Information for the patient

FABHALTA® 200 mg hard capsules
iptacopan

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What FABHALTA is and what it is used for

FABHALTA contains the active substance iptacopan, which belongs to a group of medicines called complement inhibitors.

FABHALTA is used:
- on its own in adults to treat paroxysmal nocturnal haemoglobinuria (PNH), a disease in which the immune system (the body's natural defence system) attacks and damages red blood cells. FABHALTA is used in adults who have anaemia (low levels of red blood cells) due to the breakdown of their red blood cells.
- in adults to treat patients with a disease called complement 3 glomerulopathy (C3G)
    - together with a renin-angiotensin-system inhibitor (RAS inhibitor), or
    - alone if an RAS inhibitor does not work well or cannot be used.

The active substance in FABHALTA, iptacopan, targets a protein called Factor B, which is involved in a part of the body's immune system called the "complement system".

In patients with PNH, the complement system is overactive, causing the destruction and breakdown of the red blood cells, which can lead to anaemia, tiredness, difficulty in functioning, pain, pain in the stomach (abdomen), dark urine, shortness of breath, difficulty swallowing, impotence and blood clots. By attaching to and blocking the Factor B protein, iptacopan can stop the complement system from attacking the red blood cells. This medicine has been shown to increase the number of red blood cells and thus may improve symptoms of anaemia.

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 (tissue scarring and thickening). As a result, patients with C3G often have high levels of protein in their urine (proteinuria) and progressive decline in kidney function over time. By attaching to the Factor B protein, iptacopan can reduce the deposition of C3 in the kidney. This medicine has been shown to reduce levels of protein in the urine and the decline in kidney function.

2. What you need to know before you take FABHALTA

Do not take FABHALTA
- if you are allergic to iptacopan or any of the other ingredients of this medicine (listed in section 6).
- if you have not been vaccinated against *Neisseria meningitidis* and *Streptococcus pneumoniae*, unless your doctor decides that urgent treatment with FABHALTA is needed.
- if you have an infection caused by a type of bacteria called encapsulated bacteria, including *Neisseria meningitidis*, *Streptococcus pneumoniae* or *Haemophilus influenzae* type B, before starting FABHALTA treatment.

Warnings and precautions
Serious infection caused by encapsulated bacteria
FABHALTA may increase your risk of infection caused by encapsulated bacteria, including *Neisseria meningitidis* (bacteria that cause meningococcal disease, including serious infection of the linings of the brain and of the blood) and *Streptococcus pneumoniae* (bacteria causing pneumococcal disease, including infection of the lungs, ears and blood).

Talk to your doctor before you start FABHALTA to be sure that you receive vaccination against *Neisseria meningitidis* and *Streptococcus pneumoniae*. You may also receive vaccination against *Haemophilus influenzae* type B if this is available in your country. Even if you have had these vaccinations in the past, you might still need to be revaccinated before starting FABHALTA.

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.

You should be aware that 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.

Tell your doctor immediately if you get any of the following symptoms of serious infection during treatment with FABHALTA:
- fever with or without shivers or chills
- headache and a fever
- fever and a rash
- fever with chest pain and cough
- fever with breathlessness/fast breathing
- fever with high heart rate
- headache with feeling sick (nausea) or vomiting
- headache with stiff neck or stiff back
- confusion
- body aches with flu-like symptoms
- clammy skin
- eyes sensitive to light

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.

Other medicines and FABHALTA
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription. In particular:

Tell your doctor or pharmacist if you are using certain medicines because they may stop FABHALTA from working properly:

- certain medicines used to treat bacterial infections – such as rifampicin

Tell your doctor or pharmacist if you are using any of the following medicines because FABHALTA may stop these medicines from working properly:
- certain medicines used to treat epilepsy – such as carbamazepine
- certain medicines used to prevent organ rejection after an organ transplant – such as ciclosporin, sirolimus, tacrolimus
- certain medicines used to treat migraines – such as ergotamine
- certain medicines used to treat chronic pain – such as fentanyl
- certain medicines used to control involuntary movements or sounds – such as pimozide
- certain medicines used to treat an abnormal heart rhythm – such as quinidine
- certain medicines used to treat type 2 diabetes – such as repaglinide
- certain medicines used to treat hepatitis C infection – such as dasabuvir
- certain medicines used to treat cancer – such as paclitaxel

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should also tell your doctor if you become pregnant during treatment with FABHALTA. Your doctor will discuss with you the potential risks of taking FABHALTA during pregnancy or breast-feeding.

Your doctor will decide whether you should take FABHALTA while you are pregnant only after a careful risk-benefit assessment.

It is unkown whether iptacopan, the active substance in FABHALTA, passes into human milk and may affect the breast-fed newborn/infant.

Your doctor will decide whether you should stop breast-feeding or stop FABHALTA treatment, taking into account the benefit of breast-feeding for your baby and the benefit of treatment for yourself.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines.

3. How to 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 exceed the prescribed dose.

The recommended dose is 200 mg (one capsule) to be taken by mouth twice daily (once in the morning and once in the evening). Swallow the FABHALTA capsule with a glass of water.

Taking FABHALTA at the same time each day will help you to remember when to take your medicine.

It is important that you take FABHALTA according to your doctor’s instructions. For patients with PNH, this is important to reduce the risk of breakdown of red blood cells due to PNH.

FABHALTA with food
FABHALTA can be taken with or without food.

Switching from other PNH medicines to FABHALTA
If you are switching from any other PNH medicine, ask your doctor when to start taking FABHALTA.

How long to take FABHALTA
PNH is a lifelong condition and it is expected that you will need to use FABHALTA for a long time. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you have questions about how long you will need to take FABHALTA, talk to your doctor.

If you take more FABHALTA than you should
If you have accidently taken too many capsules or if someone else accidentally takes your medicine, talk to your doctor immediately.

If you forget to take FABHALTA
If you miss a dose or doses, take one dose of FABHALTA as soon as you remember (even if it is shortly before the next scheduled dose), then take the next dose at the usual time. If you have PNH and you miss several doses in a row, contact your doctor who may decide to monitor you for any signs of the breakdown of red blood cells (see section "If you stop taking FABHALTA" below).

If you stop taking FABHALTA
Stopping your treatment with FABHALTA can make your condition worse. Do not stop taking FABHALTA without talking to your doctor first.

If you have PNH and your doctor decides to stop your treatment with this medicine, you will be monitored closely for at least 2 weeks after stopping treatment for any signs of the breakdown of red blood cells. Your doctor may prescribe a different PNH medicine or restart your FABHALTA treatment.

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

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Serious side effects

The most serious side effect is serious infection.

If you experience any of the symptoms of serious infection listed under "Serious infection caused by encapsulated bacteria" in section 2 of this leaflet, you should immediately inform your doctor.

Side effects for PNH

Very common (may affect more than 1 in 10 people)
- infections of the nose and throat (upper respiratory tract infection)
- headache

- diarrhoea

Common (may affect up to 1 in 10 people)
- persistent cough or irritation of the airways (bronchitis)
- low levels of platelets (which help the blood clot) in the blood (thrombocytopenia), which may cause you to bleed or bruise more easily
- dizziness
- pain in the stomach (abdomen)
- feeling sick (nausea)
- joint pain (arthralgia)
- urinary tract infection

Uncommon (may affect up to 1 in 100 people)
- lung infection, which can cause chest pain, cough and fever
- itchy rash (urticaria)

Side effects for C3G

Very common (may affect more than 1 in 10 people)
- infections of the nose and throat (upper respiratory tract infection)

Common (may affect up to 1 in 10 people)
- pneumococcal infection including lung infection (pneumonia) and blood infection (sepsis)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store FABHALTA

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What FABHALTA contains
- The active substance is iptacopan.
- The other ingredients are:
  - 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)

What FABHALTA looks like and contents of the pack
Pale yellow, opaque hard capsules, with "LNP200" on the body and "NVR" on the cap, containing white or almost white to pale purplish-pink powder. The capsule size is approximately 21 to 22 mm.

FABHALTA is supplied in PVC/PE/PVDC blisters with aluminium foil backing.

FABHALTA is available in
- packs containing 28 or 56 hard capsules and in
- multipacks comprising 3 cartons, each containing 56 capsules.

Not all pack sizes may be marketed.

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