

This medicine is dispensed with a doctor's prescription only

## Fabhalta®

### 200 mg, hard capsules

#### Active ingredient

Each capsule contains:

iptacopan hydrochloride monohydrate, equivalent to iptacopan 200 mg

Inactive ingredients and allergens in this medicine: see section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

**In addition to the leaflet, Fabhalta has a Patient Safety Information Card and a Patient and Caregiver Guide.**

**These education materials contain important safety information that you need to know before starting treatment and during treatment with Fabhalta and to act accordingly.**

**You should review these card and guide and the patient leaflet before you start using the product. Keep the card and guide for further reference if needed.**

#### 1. What is this medicine intended for?

Fabhalta is indicated as monotherapy in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH) who have haemolytic anaemia.

**Therapeutic group:** Immunosuppressants, complement inhibitors.

Paroxysmal nocturnal haemoglobinuria (PNH) is a disease in which the immune system (the body's natural defence system) attacks and damages red blood cells.

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 the symptoms of anaemia.

#### 2. Before using this medicine

**Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient (iptacopan) or to any of the other ingredients in this medicine (see section 6).
- You have not been vaccinated against *Neisseria meningitidis* and *Streptococcus pneumoniae*, unless your doctor decides that urgent treatment with Fabhalta is needed.
- 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.

#### Special warnings about using this medicine

##### 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 treatment** 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 Israel. Even if you have had these vaccinations in the past, you might still need to be revaccinated before starting Fabhalta treatment.

These vaccinations should be given at least 2 weeks before starting Fabhalta treatment. If this is not possible, you will be vaccinated as soon as possible after you start Fabhalta treatment, 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 fever
- fever and rash
- fever with chest pain and cough
- fever with breathlessness/fast breathing
- fever with high heart rate
- headache with 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

Fabhalta is not indicated for use in children and adolescents under 18 years of age.

There is no information regarding the safety and efficacy of using this medicine in children and adolescents.

#### Tests and follow-up

##### Laboratory tests in PNH patients

During treatment with Fabhalta, your doctor will monitor you regularly for signs and symptoms of red blood cell breakdown (haemolysis), including measuring lactate dehydrogenase (LDH) levels.

For the required follow-up after treatment discontinuation, please see "If you stop taking Fabhalta" is section 3.

#### Interactions with other medicines

**If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.** Particularly:

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 viral hepatitis C infection – such as dasabuvir
- certain medicines used to treat cancer – such as paclitaxel

#### Using this medicine and food

Swallow the medicine with a glass of water. Fabhalta can be taken with or without food.

#### Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, 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 breastfeeding.

There are limited data about taking Fabhalta during pregnancy. Your doctor will decide whether you should take Fabhalta while you are pregnant only after a careful risk-benefit assessment.

It is unknown whether iptacopan, the active substance in Fabhalta, passes into human milk and may affect the breastfed newborn/infant.

Your doctor will decide whether you should stop breastfeeding or stop Fabhalta treatment, taking into account the benefit of breastfeeding for your baby and the benefit of treatment for yourself.

#### Fertility

There are no data on the effect of Fabhalta on human fertility.

#### Driving and using machines

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

#### 3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually: 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. Can be taken with or without food.

#### Do not exceed the recommended dose.

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 to reduce the risk of breakdown of red blood cells due to PNH.

#### Switching from other PNH medicines to Fabhalta

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

#### Duration of Fabhalta treatment

PNH is a lifelong condition, and it is expected that you will need to receive 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 have accidentally taken a higher dose of Fabhalta

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

#### If you forget to take Fabhalta

If you miss a dose or several 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 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).

Adhere to the treatment as recommended by your doctor.

#### If you stop taking Fabhalta

Stopping your treatment with Fabhalta may make your condition worse. Do not stop taking Fabhalta without talking to your doctor first.

If your doctor decides to stop 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 symptoms after stopping treatment, contact your doctor.

If you have any further questions regarding treatment with this medicine, ask your doctor or pharmacist.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### 4. Side effects

As with any medicine, using Fabhalta may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

##### Serious side effects

The most commonly reported serious side effect is urinary tract 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.

##### Other side effects

**Very common side effects** (may affect more than 1 in 10 people):

- infections of the nose and throat (upper respiratory tract infection)
- headache
- diarrhoea

**Common side effects** (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)
- nausea
- joint pain (arthralgia)

**Uncommon side effects** (may affect up to 1 in 100 people):

- lung infection, which can cause chest pain, cough and fever
- itchy rash (urticaria)

##### Laboratory and vital signs

In addition to the above list, patients with PNH who received Fabhalta experienced:

- increase of cholesterol levels in their blood
- increase of their blood pressure
- decrease in heart rate

These effects are thought to occur as a consequence of the improvement of the type of anemia (low levels of red blood cells) that is typical in patients with PNH.

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

In addition, you can report to Novartis using the following email: [safetydesk.israel@novartis.com](mailto:safetydesk.israel@novartis.com)

#### 5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:**  
Do not store above 30°C.

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

#### 6. Additional information

**In addition to the active ingredient, this medicine also contains:**

- Capsule shell:
  - gelatin, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172)
- Printing ink:
  - shellac, iron oxide black (E172), propylene glycol, ammonia solution concentrated, potassium hydroxide

#### What the medicine looks like and contents of the pack:

Pale yellow, opaque hard capsules, with black axial text "LNP200" on the capsule body and "NVR" on the cap, containing white or almost white to pale purplish-pink powder.

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

Fabhalta is available in packs containing 56 hard capsules.

**Registration holder and importer and its address:** Novartis Israel Ltd., P.O.B. 9240, Tel Aviv.

Approved in January 2025.

**Registration number of the medicine in the Ministry of Health National Drug Registry:** 178-29-38091-99