

Summary report on authorisation dated 09 February 2026

Fabhalta[®] (active substance: iptacopan)

Indication extension in Switzerland: 25 September 2025

Hard capsules for the treatment of adult patients with complement 3 glomerulopathy (C3G).

About the medicinal product

Fabhalta contains the active substance iptacopan (as iptacopan hydrochloride monohydrate).

Under the present indication extension, Fabhalta can be used in adults with complement 3 glomerulopathy (C3G) in combination with a renin-angiotensin system inhibitor (RAS inhibitor) or on its own if a RAS inhibitor is unsuitable.

C3G is a rare disease in which protein deposits cause damage to the kidneys.

Since C3G is a very rare and potentially severe disease, Fabhalta has been authorised as an orphan drug (medicinal product for rare diseases) in this indication extension.

Swissmedic first authorised Fabhalta on 29 August 2024 for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH) who had not responded sufficiently to a course of C5 inhibitors lasting at least six months.

Mode of action

Iptacopan, the active substance in Fabhalta, binds to Factor B, a protein in the complement system¹, thereby inhibiting one line of immune system activation. In patients with C3G, this part of the immune system is overactive and causes inflammation and damage

in the kidneys. By blocking Factor B, Fabhalta reduces pathological complement activation. As a result, fewer complement system products are deposited in the kidneys, reducing inflammation and protecting the kidneys against further damage.

Administration

Fabhalta is a prescription-only medicine.

¹ The complement system is part of the immune system. It helps identify and combat pathogens. Dysregulation may cause tissue damage.

It is available in the form of hard capsules, with each capsule containing 200 mg of iptacopan (as iptacopan hydrochloride monohydrate).

The recommended dosage is 200 mg (1 capsule) twice daily (total dosage of 400 mg daily).

The capsules should be swallowed whole and can be taken with or without food.

In the treatment of C3G, Fabhalta is generally used in addition to existing RAS inhibitor treatment (if tolerated).

Efficacy

The efficacy of Fabhalta was investigated in a study (APPEAR-C3G) with 74 adult C3G patients who continued to display disease-related protein excretion in their urine despite RAS inhibitor treatment.

The patients were divided into 2 groups: One group received 200 mg Fabhalta twice daily, the other received a dummy medication (placebo).

After six months, Fabhalta had reduced average protein excretion in the urine by around 30%, whereas excretion increased slightly under placebo. Furthermore, kidney function remained stable in the Fabhalta group. These results were significantly better compared to the control group.

Fabhalta was not investigated in adolescents under the age of 18 years. Consequently, there are no efficacy data for this age group.

Precautions, undesirable effects, & risks

Fabhalta must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects (affecting more than 1 in 10 patients) are upper respiratory tract infections, headache, diarrhoea and abdominal pain.

Since Fabhalta affects the immune system, it may increase the risk of certain severe infections, particularly with what are known as

encapsulated bacteria, such as *Neisseria meningitidis* and *Streptococcus pneumoniae*. Patients should protect themselves by ensuring they are appropriately vaccinated before treatment starts.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Until now, there has been no authorised treatment for patients with complement 3 glomerulopathy (C3G). The disease is rare, often affects younger people, and can cause kidney failure in just a few years.

Fabhalta specifically targets complement system overactivation, the key disease mechanism in C3G. In the trial, Fabhalta significantly reduced protein excretion in the urine while maintaining stable kidney function.

Taking all the risks and precautions into account, and based on the available data, the benefits of Fabhalta outweigh the risks.

Swissmedic has therefore authorised the medicinal product Fabhalta, containing the active substance iptacopan, in Switzerland for the treatment of adult patients with C3G in combination with a RAS inhibitor or in cases where a RAS inhibitor is unsuitable.

Further information on the medicinal product

Information for healthcare professionals: [Information for healthcare professionals Fabhalta®](#)

Information for patients (package leaflet): [Information for patients Fabhalta®](#)
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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