



EUROPEAN MEDICINES AGENCY
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Rezurock (*belumosudil*)

A plain-language overview of Rezurock and why it is authorised in the EU

What is Rezurock and what is it used for?

Rezurock is a medicine used to treat chronic graft-versus-host disease (GvHD) in adults and adolescents from 12 years of age weighing at least 40 kg. It is used when all other available treatments have not worked well enough or are not suitable. Chronic GvHD is a long-term, serious and life-threatening condition, in which donor cells from a bone marrow or stem cell transplant attack the patient's body.

Chronic GvHD is rare, and Rezurock was designated an 'orphan medicine' (a medicine used in rare diseases) on 17 October 2019. Further information on the orphan designation can be found on the [EMA website](#).

Rezurock contains the active substance belumosudil.

How is Rezurock used?

The medicine can only be obtained with a prescription. Treatment should be started and supervised by a doctor experienced in the management of chronic GvHD.

Rezurock is available as tablets to be taken by mouth once a day with a meal, at approximately the same time each day. Treatment should continue for as long as chronic GvHD is under control and side effects remain manageable.

Before starting treatment, patients must have a blood test to check their blood cell levels and liver function. Liver function must be checked at least once a month while the patient is taking the medicine.

The doctor may need to reduce the dose or stop the medicine in case of side effects.

For more information about using Rezurock, see the package leaflet or contact your doctor or pharmacist.

How does Rezurock work?

The active substance in Rezurock, belumosudil, stops the action of ROCK2, a protein involved in the immune reactions that take place in chronic GvHD and cause inflammation and scarring (fibrosis) in

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different organs. By blocking the action of this protein, Rezurock is expected to help treat the condition by reducing inflammation and fibrosis.

What benefits of Rezurock have been shown in studies?

The main study involved 156 patients with chronic GvHD who had previously received at least two other treatments. Patients received Rezurock either once a day (78 patients) or twice a day (78 patients). Patients were also allowed to take other treatments, and Rezurock was not compared with any other treatment. The study looked at how many patients taking Rezurock once a day responded to treatment with either a complete response (all symptoms in all affected organs resolved) or a partial response (at least one organ improved and no other organ worsened or became affected). Over a 6-month period, 73% of patients (57 out of 78) who took Rezurock once daily responded to treatment. At 6 months, 44% of patients were responding to treatment. Around 5% of patients (4 out of 78) achieved a complete response while around 68% (53 out of 78) achieved a partial response.

What are the side effects and restrictions with Rezurock?

For the full list of side effects and restrictions with Rezurock, see the package leaflet.

The most common side effects with Rezurock (which may affect more than 1 in 10 people) include tiredness, diarrhoea, nausea (feeling sick), headache, vomiting, increased blood levels of the liver enzymes aspartate aminotransferase (AST) and alanine aminotransferase (ALT).

Some side effects can be serious. The most frequent (which may affect more than 1 in 100 people) include pneumonia (infection of the lungs), cellulitis (inflammation of the deep skin tissue), large intestine infection, periorbital cellulitis (inflammation of the eye lid and skin around the eye), staphylococcal bacteraemia (staphylococci bacteria present in the blood), upper respiratory tract infection (nose and throat infection), hypoxia (lack of oxygen in body tissues), pulmonary embolism (clot in a blood vessel in the lung), diarrhoea, nausea, tongue dysplasia (presence of abnormal cells in the tongue which may become cancerous), vomiting and multiple organ dysfunction syndrome (a serious condition where several organs in the body stop working properly).

Why is Rezurock authorised in the EU?

At the time of approval, there was an urgent medical need for new treatments for patients with chronic GvHD when other treatments have failed or are not suitable. The main study showed that treatment with Rezurock could lead to a response in patients with chronic GvHD. However, there are uncertainties about the size of the benefit because of how the main results were measured and because patients were taking other treatments at the same time.

Side effects were generally manageable and acceptable, given the lack of treatment options for these patients.

Rezurock has been given conditional authorisation for use in the EU. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The European Medicines Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Rezurock. It must carry out a c study where Rezurock is compared to another treatment to confirm its effectiveness. Every year, the Agency will review any new information that becomes available.

What measures are being taken to ensure the safe and effective use of Rezurock?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Rezurock have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Rezurock are continuously monitored. Suspected side effects reported with Rezurock are carefully evaluated and any necessary action taken to protect patients.

Other information about Rezurock

Rezurock received a conditional marketing authorisation valid throughout the EU on 24 March 2026.

Further information on Rezurock, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/rezurock.

For information about the availability of this medicine in your country, contact your [national competent authority](#).

This overview was last updated in 03-2026.