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# Lytenava (*bevacizumab gamma*)

An overview of Lytenava and why it is authorised in the EU

## What is Lytenava and what is it used for?

Lytenava is a medicine used to treat adults with the 'wet' form of age-related macular degeneration (AMD), a disease that affects the central part of the retina (called the macula) at the back of the eye. The wet form of AMD is caused by abnormal growth of blood vessels beneath the retina which may leak fluid and blood and cause swelling.

Lytenava contains the active substance bevacizumab gamma.

## How is Lytenava used?

Lytenava can only be obtained with a prescription. It is available as a solution for intravitreal injection (injection into the vitreous humour, the jelly-like fluid inside the eye) and must be given by a qualified healthcare professional who is experienced in giving such injections.

Treatment is started with one injection every month, with regular checks of the patient's vision and examination of the back of the eye, until maximum vision is achieved or there are no signs of disease activity. After that, the doctor may adjust the interval between doses after assessing the patient's vision and depending on disease activity. Treatment with Lytenava should be stopped if the patient is not benefitting from it.

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

## How does Lytenava work?

The active substance in Lytenava, bevacizumab gamma, is a monoclonal antibody (a type of protein). It has been designed to attach to vascular endothelial growth factor (VEGF), a protein that circulates in the blood and makes blood vessels grow. By attaching to VEGF, bevacizumab is expected to block its activity. This will slow down the growth of blood vessels in the eye, reducing fluid leakage and swelling.

## What benefits of Lytenava have been shown in studies?

The benefits of Lytenava were investigated in two main studies involving almost 300 adults with the wet form of AMD.

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In these studies, patients were given either Lytenava or ranibizumab (another substance used to treat wet AMD). Lytenava was given as a monthly injection into the eye for up to 12 months. Ranibizumab was given in a non-authorised regimen as a monthly injection for the first three months followed by two additional doses given three months after the previous injection. To make sure that patients did not know if they received Lytenava or ranibizumab, patients received a sham injection (a procedure in which the syringe is pressed against the surface of the eye but no actual injection is carried out) in months when they were not scheduled to receive ranibizumab. Both studies looked at the proportion of patients in whom vision had improved after 11 months of treatment, measured as an increase of 15 or more in the number of letters that they could recognise on a standard eye test.

The first main study, which included previously treated and untreated patients, compared 31 patients given Lytenava for up to 12 months with 30 patients given ranibizumab or sham injections. The study did not demonstrate an improvement in vision in patients given Lytenava compared with patients given ranibizumab.

The second main study compared 113 patients given Lytenava with 115 patients given ranibizumab or sham injections. The majority of patients had not been treated before. After 11 months, vision had improved in 41.7% of patients given Lytenava, compared with 23.1% of patients given ranibizumab.

Because authorised medicines with the same active substance (bevacizumab) have been used off-label to treat wet AMD, the company presented supporting literature data from 3 studies in patients with wet AMD that compared intravitreal injection of bevacizumab medicines with ranibizumab. These studies showed a beneficial effect of bevacizumab in the treatment of wet AMD.

## What are the risks associated with Lytenava?

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

The most common side effects with Lytenava (which may affect up to 1 in 10 people) include conjunctival haemorrhage (bleeding at the front of the eye), vitreous floaters (spots in the vision), eye pain and increased intraocular pressure (pressure within the eye). The most serious side effects (which may affect up to 1 in 100 people) include increased intraocular pressure, temporary blindness, endophthalmitis (an infection inside the eye) and inflammation within the eye.

## Why is Lytenava authorised in the EU?

Although there are uncertainties regarding the effectiveness of Lytenava over the comparator, the medicine has shown beneficial effects that are considered relevant for patients with wet AMD. The safety of Lytenava was considered similar to that of alternative medicines and was considered acceptable. The Agency therefore decided that Lytenava’s benefits are greater than its risks and that it can be authorised for use in the EU.

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

The company that markets Lytenava will provide educational materials for patients with information about wet AMD, how Lytenava works and how it is given, and what to expect from the treatment. The patient guide will also include information about Lytenava’s side effects and on when to seek urgent medical attention after treatment with the medicine.

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

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

## Other information about Lytenava

Lytenava received a marketing authorisation valid throughout the EU on 27 May 2024.

Further information on Lytenava can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/lytenava

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