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Vabysmo (*faricimab*)

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

What is Vabysmo and what is it used for?

Vabysmo 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;
- impaired vision due to macular oedema (swelling) caused by diabetes;
- impaired vision due to a swelling of the macula caused by retinal vein occlusion (RVO, a blockage of the blood flow in a vein of the retina).

The macula provides central vision that is needed to see details for everyday tasks such as driving, reading and recognising faces. The diseases cause the gradual loss of the central part of a person's vision.

Vabysmo contains the active substance faricimab.

How is Vabysmo used?

Vabysmo can only be obtained with a prescription and must be given by a qualified eye doctor who is experienced in giving injections into the eye.

It is given as an injection into the vitreous humour, the jelly-like fluid inside the eye. Treatment starts with one injection every four weeks. After several doses, the doctor may adjust the interval after assessing the patient's vision. Treatment with Vabysmo should be stopped if the patient is not benefitting from it.

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

How does Vabysmo work?

The active substance in Vabysmo, faricimab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to two proteins: vascular endothelial growth factor A (VEGF-A) and angiopoietin-2 (Ang-2).

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In patients with wet AMD and macular oedema caused by diabetes or retinal vein occlusion, these two proteins increase the permeability of blood vessels and stimulate their growth, causing fluid and blood leakage, which damages the macula. By attaching to VEGF-A and Ang-2, faricimab blocks the action of these proteins, thereby reducing the permeability and growth of the blood vessels and controlling the leakage, swelling and inflammation.

What benefits of Vabysmo have been shown in studies?

AMD

Two main studies involving 1,329 patients with the wet form of AMD showed that Vabysmo given at up to 16-week intervals was at least as effective at improving the condition as aflibercept (another medicine for the wet form of AMD) given at 8-week intervals. After a year of treatment, the average number of letters patients could recognise on a standard eye test improved by 5.8 (first study) and 6.6 letters (second study) in patients treated with Vabysmo, and by 5.1 and 6.6 letters for those given aflibercept.

Diabetic macular oedema

Two main studies involving 1,891 patients with diabetic macular oedema looked at the effect of Vabysmo given either at 8-week intervals or at adjustable intervals (up to 16 weeks), and of aflibercept given at 8-week intervals.

After a year of treatment, the improvement in the number of letters patients could recognise was similar for the different treatments. In the first study, this improved by 10.7 letters for patients given Vabysmo every 8 weeks, by 11.6 letters for those given Vabysmo at variable intervals, and by 10.9 letters for those given aflibercept. In the second study, the improvements were 11.8, 10.8 and 10.3 letters, respectively. In both studies, this effect was maintained throughout a second year of treatment.

Macular oedema caused by RVO

Two main studies involving 1,282 patients with macular oedema caused by RVO showed that Vabysmo was at least as effective as aflibercept at improving their vision. After 24 weeks of treatment (6 doses at 4-week intervals), the average number of letters patients could recognise on a standard eye test improved by 16.9 letters in patients treated with Vabysmo, compared with 17.5 (first study) and 17.3 (second study) in patients given aflibercept. After 24 weeks of treatment, patients continued Vabysmo at 4 to 16-week intervals. In both studies, the effect of Vabysmo was maintained until week 72.

What are the risks associated with Vabysmo?

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

The most common side effects with Vabysmo (which may affect up to 1 in 10 people) include cataract (clouding of the lens), bleeding of the conjunctiva (the membrane that lines the white of the eye and the inside of the eyelid), increased pressure within the eye, vitreous floaters (small, dark shapes moving in the field of vision), eye pain, tears of the retinal pigment epithelium (only in patients with wet AMD) and increased lacrimation (watery eyes).

The most serious side effects with Vabysmo (which may affect up to 1 in 100 people) include uveitis (inflammation of the uvea, the layer beneath the white of the eyeball), vitritis (the presence of inflammatory cells in the vitreous humour), endophthalmitis (inflammation inside the eye), retinal tear and rhegmatogenous retinal detachment (the most common type of retinal detachment). Another serious side effect is traumatic cataract which may affect less than 1 in 1,000 patients.

Vabysmo must not be used in patients who may have an infection of the eye or the area around the eye, or who have a severe inflammation within the eye.

Why is Vabysmo authorised in the EU?

Vabysmo was shown to be as effective as the comparator aflibercept at improving the vision of patients with wet AMD and macular oedema caused by diabetes or RVO. Regarding safety, the most common side effects of Vabysmo are similar to those of other products given by intravitreal injection and are considered acceptable.

The European Medicines Agency therefore decided that Vabysmo's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Vabysmo will provide an information pack to patients to help them prepare for treatment, recognise signs and symptoms of serious side effects and know when to seek urgent attention from their doctor.

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

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

Other information about Vabysmo

Vabysmo received a marketing authorisation valid throughout the EU on 15 September 2022.

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

This overview was last updated in 08-2024.