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Bekemv (eculizumab)

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

What is Bekemv and what is it used for?

Bekemv is a medicine used to treat adults and children with paroxysmal nocturnal haemoglobinuria (PNH), a disease in which excessive breakdown of blood cells results in anaemia (low levels of red blood cells), thrombosis (blood clots in blood vessels), pancytopenia (low levels of blood cells) and dark urine.

Bekemv is a 'biosimilar medicine'. This means that Bekemv is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Bekemv is Soliris. For more information on biosimilar medicines, see here.

Bekemv contains the active substance eculizumab.

How is Bekemv used?

The medicine can only be obtained with a prescription and should be given by a healthcare professional and under the supervision of a doctor familiar with blood diseases.

Bekemv is given as an infusion (drip) into a vein over 25 to 45 minutes (adults) or 1 to 4 hours (children) every week for the first 2 to 5 weeks and every 2 weeks thereafter. Patients are monitored for any reactions during the infusion and for at least one hour afterwards.

Patients who have no major side effects with the first infusions may be able to have their infusions given at home by a healthcare professional.

Bekemv should be given for life unless the patient develops serious side effects.

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

How does Bekemv work?

The complement system is a set of proteins that is part of the immune system (the body's natural defences). In patients with PNH, the complement system is over-active and damages the patients' own blood cells.

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The active substance in Bekemv, eculizumab, is an antibody (a type of protein) designed to attach to the C5 protein of the complement system. By blocking C5, eculizumab prevents the complement system from damaging cells, thereby helping to relieve the symptoms of the disease.

What benefits of Bekemv have been shown in studies?

Laboratory studies comparing Bekemv with Soliris have shown that the active substance in Bekemv is highly similar to that in Soliris in terms of structure, purity and biological activity. Studies have also shown that giving Bekemv produces similar levels of the active substance in the body to giving Soliris.

In addition, a study involving 42 patients with PNH showed that Bekemv and the reference medicine, Soliris, prevented the breakdown of red blood cells in a similar manner.

Because Bekemv is a biosimilar medicine, the studies on effectiveness and safety of eculizumab carried out with Soliris do not all need to be repeated for Bekemv.

What are the risks associated with Bekemv?

The safety of Bekemv has been evaluated, and based on all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine Soliris.

For the complete list of side effects and restrictions of Bekemv, see the package leaflet.

The most common side effect with Bekemv (which may affect more than 1 in 10 people) is headache and the most serious side effect is meningococcal sepsis (when a bacteria infects the bloodstream, causing bleeding of the skin and organs).

Bekemv must not be given to children below 2 years of age, and to patients with a hereditary fructose intolerance (HFI, inherited inability to digest fructose (fruit sugar)). It must also not be given to patients who have an ongoing infection by the bacteria *Neisseria meningitidis,* or those who are not currently vaccinated against it unless they receive antibiotics to prevent infection until 2 weeks after vaccination.

Why is Bekemv authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Bekemv has a highly similar structure, purity and biological activity to Soliris and is distributed in the body in the same way. In addition, studies in patients with PNH have shown that the safety and effectiveness of Bekemv is equivalent to that of Soliris.

All these data were considered sufficient to conclude that Bekemv will behave in the same way as Soliris in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Soliris, the benefits of Bekemv outweigh the identified risks and it can be authorised for use in the EU.

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

The company that markets Bekemv will ensure that the distribution of the medicine occurs only after checking that the patient has been vaccinated appropriately and will send reminders to prescribers or pharmacists to check the vaccination status of patients.

The company will provide prescribers and patients with a guide on the safety of the medicine. Patients will also be given a 'safety card' that explains the symptoms of certain types of infection, instructing patients to seek medical care immediately if they experience them, and will include a reminder that the medicine must not be given to children below 2 years of age and to patients who have HFI.

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

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

Other information about Bekemv

Bekemv received a marketing authorisation valid throughout the EU on 19 April 2023.

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

This overview was last updated in 04-2023.