BEKEMV®▼(eculizumab)

Guide for Patients/ Parents/Caregivers

Important safety information to minimise the risk of serious side effects associated with the use of BEKEMV

This guide is a required safety measure to help ensure the medicine is used as safely as possible. It has been reviewed and approved by the health authority.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get via the instructions given in section “Reporting of Side Effects”

AMGEN®

BEKEMV®_Guide for Patients/Parents/Caregivers_Version 2, September 2025
Ireland

CONTENTS PAGE

SUMMARY OF IMPORTANT RISKS AND RECOMMENDED ACTIONS FOR THEIR PREVENTION AND/OR MINIMISATION

When you start treatment with BEKEMV, you will receive this guide, a Patient Card and the Package Leaflet. Additional copies of any of these materials can be requested from your doctor or can be found on the following website https://www.medicines.ie/.

Read all the information provided and speak to your/your child's doctor if you have any questions.

Risk of meningococcal infection and other infections

BEKEMV increases the risk of developing meningococcal infection, sepsis and other infections.

- It is very important that you learn to recognise the symptoms of meningitis and contact your doctor **immediately** if you notice any symptoms.
- Meningitis and sepsis are extremely dangerous infections that can quickly become life-threatening or fatal if not treated promptly.
- All patients treated with BEKEMV will need to be vaccinated against the bacteria that causes meningococcal meningitis at least 2 weeks before starting therapy and/or take antibiotics. Patients under 18 years of age will also need to be vaccinated against *Haemophilus influenzae* type B.

Patients prescribed BEKEMV for the treatment of atypical hemolytic uremic syndrome (aHUS)

Temporary or permanent discontinuation of BEKEMV may cause aHUS symptoms to return.

Patients with hereditary fructose intolerance (HFI)

If you have HFI, a rare genetic disorder, you must not receive this medicine because it contains sorbitol (a source of fructose). People with HFI cannot break down fructose, which may cause serious side effects.

Babies and children below 2 years of age must not receive this medicine. In babies and children below 2 years of age HFI may not yet be diagnosed.

Please see the sorbitol content warning on the last page of this guide.

IMPORTANT SAFETY INFORMATION FOR BEKEMV

Risk of meningococcal infection and other infections

As BEKEMV blocks a part of the immune system, it increases the risk of severe infection and sepsis (serious and potentially life-threatening infection in the bloodstream), especially by a type of bacteria called *Neisseria meningitidis*. This can cause cases of meningococcal infection, also known as meningitis (can cause a severe infection of the linings of the brain and/or blood infection).

BEKEMV may reduce your natural resistance to other similar bacterial infections including disseminated gonorrhoea. This is a sexually transmitted infection caused by the bacterium Neisseria gonorrhoeae (also named gonorrhoea). Signs and symptoms can include joint pain or inflammation, painful inflammation surrounding a tendon, and skin lesions. It can also lead to sepsis.

These infections require immediate and appropriate care as they can quickly become life-threatening or fatal if not treated promptly.

Before starting treatment with BEKEMV

- Your doctor will vaccinate you/your child against meningococcal infection at least 2 weeks before starting treatment. If BEKEMV is started less than 2 weeks after receiving a meningococcal vaccine, your doctor will make sure that you take antibiotics for 2 weeks after the vaccination to reduce the risk of infection.
  - Vaccination reduces the risk of developing meningococcal infection but does not completely eliminate it. Your doctor may consider that you need additional measures to prevent infection.
- If you/your child is less than 18 years of age, you/they must also be vaccinated against *Haemophilus influenzae* and pneumococcal infections according to national vaccination guidelines.

Meningococcal vaccination is required prior to the start of treatment with BEKEMV. Revaccination is required in accordance with current national vaccination guidelines for vaccination use.

Ask your doctor if you have any questions about the vaccinations you need.

During treatment with BEKEMV

You will need to be aware of the signs and symptoms of potential meningococcal infection which includes:

- Headache with nausea or vomiting
- Headache with a stiff neck or back
- Fever
- Rash
- Confusion
- Severe muscle ache combined with flu-like symptoms
- Sensitivity to light

If you are a caregiver of a child who is receiving BEKEMV, it is important to be aware that certain signs and symptoms of meningitis and/or sepsis can be difficult to detect:

Other possible signs and symptoms in infants and children include:

- Rapid breathing
- Cold hands and feet
- Refusing food and/or vomiting
- Unusual crying or moaning
- Stiff neck
- Being drowsy or difficult to wake
- Irritability
- Convulsions/seizures

The symptoms of meningitis can appear in any order. Some may not appear at all. It is very important to seek medical attention immediately if you notice any of the signs and symptoms listed above.

If you cannot reach your doctor, go to an Accident & Emergency department and show them your/your child's Patient Card.

PATIENT CARD

Your doctor will give you a Patient Card. It includes a list of symptoms of meningitis infection, which is important to identify so treatment can be started promptly.

- You must carry this card with you at all times while you are taking BEKEMV and for 3 months after your last dose.
- Tell any healthcare professional that you are being treated with this medicine and show them the card.

DISCONTINUATION OF BEKEMV IN PATIENTS WITH ATYPICAL HEMOLYTIC UREMIC SYNDROME (aHUS)

If BEKEMV treatment is stopped completely, or postponed (or if treatments are missed), there is a risk that one of the serious features of your/your child's condition could occur. This includes the risk of thrombotic microangiopathy (abnormal blood clotting in small vessels), Symptoms may include shortness of breath, confusion (or change in how alert you/your child are), chest pain or angina.

If you plan to stop treatment with BEKEMV, you need to discuss beforehand with your/your child's doctor the possible side effects and risks.

If you do stop BEKEMV, your doctor will monitor you carefully.

SORBITOL CONTENT WARNING

This medicine contains 50 mg sorbitol in each mL.

Sorbitol is a source of fructose. If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or your child) must not receive this medicine. Patients with HFI cannot break down fructose, which may cause serious side effects, like seizures, coma, growth retardation, kidney and liver failure.

You must tell your doctor before receiving this medicine if you (or your child) have HFI or if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.

Babies and children below 2 years of age must not receive this medicine. In babies and children below 2 years of age HFI may not yet be diagnosed.

REPORTING OF SIDE EFFECTS

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

Please report any potential quality issue with the Amgen product you have received, by calling us on +44 (0) 1223 436441 or Freephone 1800 535 160 and providing us with the details. Please ensure that you keep your packaging, so we are able to identify your product more easily.

MORE INFORMATION

If you require further information on BEKEMV, please contact Amgen Medical Information by telephone on +44 (0) 1223 436441, Freephone 1800 535 160 or email gbinfoline@amgen.com.