

BEKEMV[®] ▼ (eculizumab)

Patient/Parent Information

**Important safety information to minimise
the risk of serious side effects**

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. 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. You can also report side effects directly via the Yellow Card Scheme at <https://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine. Side effects can also be reported to Amgen Limited on +44 (0) 1223 436441.

AMGEN

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INTRODUCTION

This brochure is for adult patients and parents/legal guardians of a child who has been prescribed BEKEMV (eculizumab). The brochure provides you with important safety information that you must be aware of.

BEKEMV¹ is used to treat adults and children with: Paroxysmal nocturnal haemoglobinuria (PNH) or atypical haemolytic uraemic syndrome (aHUS).

In babies and children below 2 years of age, Hereditary fructose intolerance (HFI), a rare genetic disorder, may not yet be diagnosed. Please see sorbitol content warning below.

FREQUENTLY ASKED QUESTIONS

WHAT INFORMATION WILL I RECEIVE?

You will receive a starter kit containing this brochure and:

- Patient Safety Card: The Patient Safety Card lists specific symptoms which you should always look out for – it is vital to be able to rapidly identify and treat certain types of infection in people who receive BEKEMV (eculizumab). You/your child should carry this card at all times and show it to any health care professional you/your child see(s).

If you don't have any of the above documentation, you can request it from your doctor.

WHAT STEPS SHOULD I TAKE BEFORE STARTING BEKEMV?

- Ensure you/your child's vaccination status is up to date.
- Be aware of the symptoms associated with infections and what to do if you/your child experience(s) any of these symptoms.
- Ensure that you communicate with your/your child's doctor and follow their advice – this ensures that you/your child receive(s) appropriate monitoring when on treatment or if the treatment is discontinued.

SORBITOL CONTENT WARNING

This medicine contains 50 mg sorbitol (E420) in each mL and it is given intravenously. BEKEMV must not be given to babies and young children below 2 years of age. In babies and children below 2 years of age Hereditary fructose intolerance (HFI) may not yet be diagnosed. HFI is a rare genetic disorder where patients cannot break down fructose or sorbitol and may have serious or life threatening side effects when exposed to them, including seizures and coma. If you/your child have HFI, you/your child must not receive this medicine. If your child is less than 2 years of age, he/she may not yet be diagnosed with HFI and treatment with BEKEMV must not be used.

Discuss with your healthcare provider if you have a family history of HFI and provide a detailed history of your/your child's dietary habits before starting treatment with BEKEMV.

I AM A PATIENT / I AM A PARENT/LEGAL GUARDIAN OF A CHILD WHO HAS BEEN PRESCRIBED BEKEMV. WHAT ADDITIONAL SAFETY PRECAUTIONS DO I NEED TO KNOW ABOUT BEFORE COMMENCING TREATMENT?

As eculizumab blocks a part of the immune system, it increases the risk of severe infection and sepsis (a 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 (severe infection of the linings of the brain and/or blood infection) and other *Neisseria* infections including disseminated gonorrhoea. **These infections require urgent and appropriate care as they may become rapidly fatal or life-threatening or lead to major disabilities.** To reduce the risk of severe infections, you/your child will need to take certain precautions detailed in this brochure.

REQUIRED VACCINATIONS

1. To reduce the risk of developing infection, at least two weeks before starting BEKEMV, you/your child:

- Must be vaccinated against meningococcal infections

Or

- If BEKEMV treatment is started less than 2 weeks after you/your child receives these vaccines, then you/your child must be given appropriate antibiotics for 2 weeks after you/your child are given the vaccine

2. If you/your child is less than 18 years of age, they must also be vaccinated against Haemophilus influenzae and pneumococcal infections according to national vaccination guidelines.

If the vaccine is not suitable for you/your child (contraindicated), you/your child will be given an antibiotic throughout the treatment period.

If you/your child has not received a meningococcal vaccine or antibiotics, speak to your doctor immediately before treatment with BEKEMV begins.

The signs and symptoms of meningococcal infection in adults and children you must look for are:

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

Meningococcal infections are extremely dangerous and may become life-threatening within hours. Early symptoms of meningitis in young children can include:

- Fever
- Headache
- Vomiting
- Diarrhoea
- Muscle pain
- Stomach cramps
- Fever with cold hands and feet

Common Signs and Symptoms of Meningitis and Severe Blood Infection (Sepsis) in children receiving eculizumab include:



- Fever, cold hands, and feet
- Fretful, dislike being handled
- Rapid breathing or grunting
- Unusual cry, moaning
- Stiff neck, dislike bright lights
- Refusing food and vomiting
- Drowsy, floppy, unresponsive
- Pale, blotchy skin spots/rash
- Convulsions/ Seizures
- Severe muscle pain
- Severe headache
- Confusion
- Irritability

WHEN SHOULD I SEEK URGENT MEDICAL ATTENTION?

The signs and symptoms of sepsis or meningitis can appear in any order. Some may not appear at all. Notify your doctor immediately if ANY of the aforementioned symptoms occur.

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

ARE THERE SERIOUS SIDE EFFECTS WITH ECULIZUMAB?

Allergic and infusion reactions

Notify your doctor immediately if any of the following symptoms of severe allergic reaction (anaphylaxis) or of any symptoms presenting during or shortly after the infusion administration occur:

- Swelling of the throat and mouth
- Difficulty breathing
- Lightheadedness
- Confusion
- Blue skin or lips
- Collapsing/losing consciousness

WHAT DO I DO IF I/MY CHILD WANT(S) TO STOP TREATMENT?

You must not stop your treatment without medical supervision.

It is very important to make sure that you/your child do/does not miss or postpone any scheduled treatment appointments in order to continue experiencing the full benefits of BEKEMV therapy.

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 or your child stop treatment with BEKEMV for aHUS

- If BEKEMV treatment is stopped completely, or postponed (or if treatments are missed), there is a risk that one of the severe complications of your/your child's condition could occur. This includes thrombotic microangiopathy, where blood clots can form in smaller blood vessels. Symptoms and signs may include a large drop in the number of red blood cells (anaemia), a large drop in the number of platelets (cells within the blood that are important for blood clotting) (thrombocytopenia), shortness of breath, confusion (or change in how alert you are) and chest pain (angina). It may also lead to damage to organs, with the kidneys particularly affected in aHUS. This can result in decreased urination and an increase in a blood marker of kidney function called creatinine.

If you or your child stop treatment with BEKEMV for PNH

- 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. Your doctor will monitor you closely for at least 8 weeks. Haemolysis is a serious feature of PNH - the red cells in the blood that carry oxygen around the body break apart. This can result in many of the symptoms and signs associated with PNH, such as, fatigue, shortness of breath, rapid heartbeat, dark urine, a large drop in the number of red blood cells (anaemia), confusion or change in how alert you are, chest pain (angina), problems with your kidneys (reduced urination, an increase in a blood marker of kidney function called creatinine), and an increased risk of blood clots (thrombosis) occurring in key parts of the body.

REPORTING OF SIDE EFFECTS

Please report any side effects to the Yellow Card Scheme at <https://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Reports can also be made to Amgen directly by contacting Medical Information by email to gbinfoline@amgen.com or telephone 01223 436441.

MORE INFORMATION

If you require further information on BEKEMV please contact Amgen Medical Information by email to gbinfoline@amgen.com or telephone 01223 436441.

HOME HEALTHCARE SERVICE

A Homecare Infusion Service is available to patient's prescribed BEKEMV subject to recommendation from your treating physician. For more details please ask your physician about this service and availability.

GLOSSARY OF TERMS

Anaphylactic reaction

Extreme and severe hypersensitivity reaction affecting the whole body, often starting with itchy rash, throat and/or tongue swelling, shortness of breath, vomiting.

Gonococcal infection

A sexually transmitted infection and caused by the bacterium *Neisseria gonorrhoeae* (also named gonorrhoea). Clinical symptoms and signs can include arthritis (painful inflammation of one or more joints), arthralgias (joint pain), tenosynovitis (painful inflammation surrounding a tendon), and multiple skin lesions. Can disseminate and cause widespread blood infection (sepsis).

Meningococcal infection

Infection caused by the bacterium *Neisseria meningitidis* (also named meningococcus). Can cause meningitis or widespread blood infection (sepsis).

Sepsis

The presence of bacteria (bacteraemia), other infectious organisms, or toxins created by infectious organisms in the bloodstream.

REFERENCES

1. BEKEMV® (eculizumab) Patient Information Leaflet available here: <https://www.medicines.org.uk/emc>
2. NHS. Meningitis symptoms. Available from: <https://www.nhs.uk/conditions/meningitis/symptoms> [Accessed September 2024]
3. NHS. Allergy symptoms. <https://www.nhs.uk/conditions/allergies/symptoms/> [Accessed September 2024]
4. NHS. Gonorrhoea. <https://www.nhs.uk/conditions/gonorrhoea/> [Accessed September 2024]
5. Hereditary Fructose Intolerance: <https://www.ncbi.nlm.nih.gov/books/NBK333439>

