

**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://yellowcard.mhra.gov.uk> 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 should also be reported to Amgen Limited on +44 (0) 1223 436441.

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## INTRODUCTION

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

BEKEMV must not be given to babies and young children below 2 years of age, please see sorbitol content warning below.

## FREQUENTLY ASKED QUESTIONS

### WHAT INFORMATION WILL I RECEIVE?

You will receive a starter kit containing:

- 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).
- Patient/Parent Information Brochure.

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 his/her advice – this ensures that you/your child receives 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. Hereditary fructose intolerance (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 (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. To reduce the risk of severe infections, you/your child will need to take certain precautions detailed in this brochure.

## REQUIRED VACCINATIONS

To reduce the risk of developing infection you/your child:

- Must be vaccinated against meningococcal infections
- 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 at least 2 weeks before starting BEKEMV therapy

Or

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

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

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

## You will need to be aware of the signs and symptoms of:

### Severe infection

- Headache with nausea or vomiting
- Headache with a stiff neck or back
- Fever
- Rash
- Confusion
- Severe muscle ache combined with flu-like symptoms
- Dislike of bright lights

### Meningitis and sepsis

If you are a parent/legal guardian of a child who is receiving BEKEMV, it is important to be aware that signs and symptoms of meningitis and/or sepsis can vary according to your child's age.



**Additional signs and symptoms to those listed above may include:**

- Rapid breathing
- Cold hands and feet
- Refusing food and/or vomiting
- Unusual crying or moaning

**Older children may also develop additional signs and symptoms to those listed above and may include:**

- Stiff neck
- Being drowsy or difficult to wake
- Irritability
- Shaking and leg pain

## WHEN SHOULD I SEEK URGENT MEDICAL ATTENTION?

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 or your child have been prescribed BEKEMV to treat atypical haemolytic uraemic syndrome (aHUS), you need to be aware of the following:**

- 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 complication is called thrombotic microangiopathy. Blood clots form in small blood vessels and this can lead to damage to organs, with the kidney particularly affected in aHUS.

**If you or your child have been prescribed BEKEMV to treat paroxysmal nocturnal haemoglobinuria (PNH), you need to be aware of the following:**

- 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. Haemolysis is a serious feature of PNH - the red cells in the blood that carry oxygen around the body break apart. Haemolysis is linked with many of the symptoms of PNH, and with an increased risk of blood clots forming in key parts of the body.

**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.**

## REPORTING OF SIDE EFFECTS

Please report any side effects to the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk> 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 at [gbinfoline@amgen.com](mailto:gbinfoline@amgen.com) or telephone 01223 436441.

## MORE INFORMATION

If you require further information on BEKEMV please contact Amgen Medical Information by email at [gbinfoline@amgen.com](mailto: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**

Infection sexually transmitted 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 Current Package Leaflet. Available from: <https://www.medicines.org.uk/emc>
2. NHS. Meningitis symptoms. Available from: <https://www.nhs.uk/conditions/meningitis/symptoms/> [Accessed February 2020]
3. NHS. Allergy symptoms. <https://www.nhs.uk/conditions/allergies/symptoms/> [Accessed February 2020]
4. NHS. Gonorrhoea. <https://www.nhs.uk/conditions/gonorrhoea/> [Accessed February 2020]
5. Hereditary Fructose Intolerance: <https://www.ncbi.nlm.nih.gov/books/NBK333439/>

