

BEKEMV[®] ▼ (eculizumab)

Patient/Parent Information

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

- ▼ You can help by reporting any side effects you may get via the instructions given in section "Reporting of Side Effects"



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This document is approved by the Executive Directorate of Pharmacovigilance at SFDA

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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.

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. 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 infections in people who receive 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 ECULIZUMAB ?

- 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 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.

I AM A PATIENT / I AM A PARENT/LEGAL GUARDIAN OF A CHILD WHO HAS BEEN PRESCRIBED ECULIZUMAB. 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 eculizumab therapy

Or

- If eculizumab 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 eculizumab 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 eculizumab, it is important to be aware that signs and symptoms of meningitis and/or sepsis can vary according to your child's age.

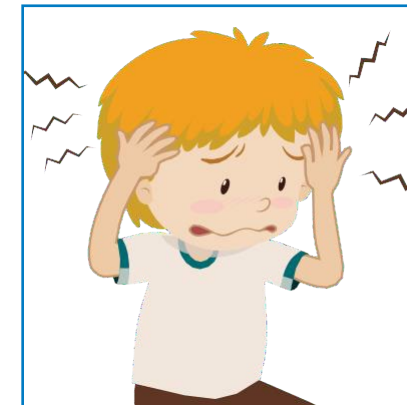


Additional signs and symptoms to those listed above may include:

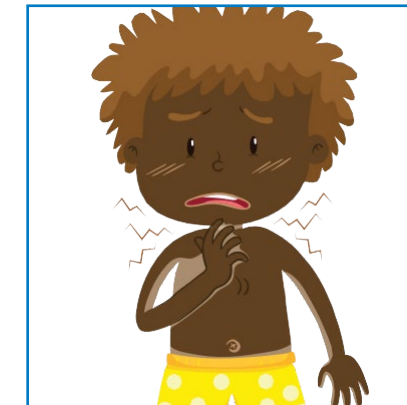
- Rapid breathing
- Cold hands and feet
- Refusing food and/or vomiting
- Unusual crying or moaning

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



Severe headache



Neck stiffness



Fever



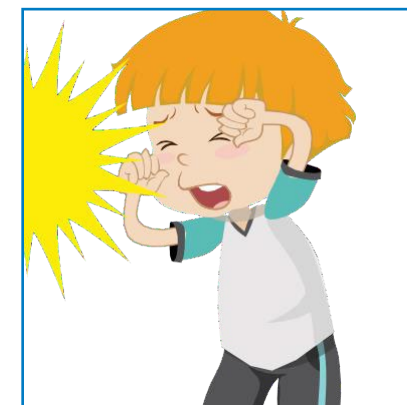
Pale, stained skin, rash



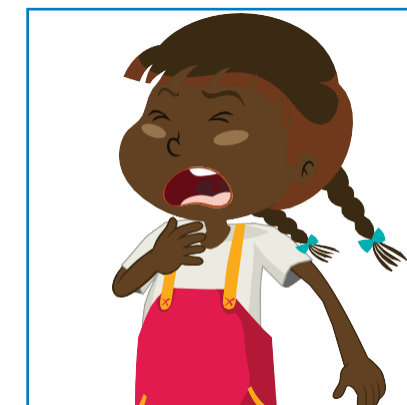
Confusion, irritability



Cramps



Dislike of bright lights



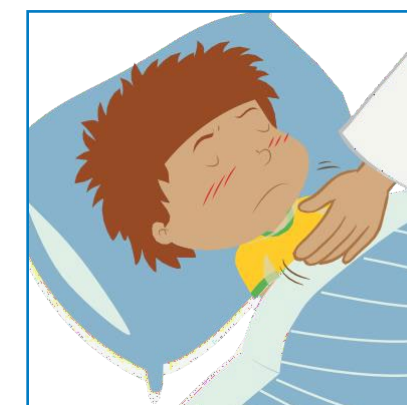
Breathing problems



Cold hands/feet



Vomiting



Sleepiness, difficult to wake up



Pain in the legs

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 eculizumab therapy.

If you or your child have been prescribed Eculizumab, you need to be aware of the following:

- If eculizumab 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 paroxysmal nocturnal hemoglobinuria (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 eculizumab, you need to discuss beforehand with your/your child's doctor the possible side effects and risks.

REPORTING OF SIDE EFFECTS

Contact details for adverse event reporting or to request further information. Any suspected adverse reactions should be reported immediately to local Amgen safety contacts or the National Pharmacovigilance Center

Amgen Local Safety Contacts
Tel: +966 112 799328
E-mail: safety-mea@amgen.com

The National Pharmacovigilance Centre (NPC)
Saudi Food and Drug Authority (SFDA)
SFDA call center 19999
E-mail: npc.drug@sfd.gov.sa Online: <http://ade.sfd.gov.sa/>

Should you have any questions or require additional information regarding the use of BEKEMV, you can refer to the patient information leaflet, or contact Medical Information by e-mail at: medinfo-mea@amgen.com

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

