BEKEMV®▼(eculizumab) PATIENT SAFETY CARD

Important Safety Information for Patients Receiving eculizumab

Show this card to any doctor involved in your care.

Eculizumab can lower the ability of your immune system to fight infections. Serious infections including sepsis may develop, **especially meningococcal infection, which requires immediate medical attention.** If you experience any of the following symptoms, you should immediately call your doctor.

If you cannot reach your doctor, go to an Accident and Emergency department and show them this card.

- Headache with nausea or vomiting
- Headache with a stiff neck or stiff back
- Fever (raised temperature)
- Rash
- Confusion
- Muscle aches with flu-like symptoms
- Eyes sensitive to light

Seek emergency medical care immediately if you have any of these signs or symptoms and show this card.

Even if you stop using eculizumab, keep this card with you for 3 months after your last eculizumab dose. Your risk of meningococcal infection may continue for a long time after your last dose of eculizumab.

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 delay (in children), kidney and liver failure.

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Information for the Treating Doctor

This patient has been prescribed eculizumab, which increases the patient's susceptibility to meningococcal infection *(Neisseria meningitidis)* **and other general infections.**

- Meningococcal infections may become rapidly life-threatening or fatal if not recognized and treated early
- **Evaluate immediately if infection is suspected and treat with appropriate antibiotics if necessary**
- Eculizumab is contraindicated in patients with HFI regardless of their age, and in babies and children under 2 years of age who may not yet be diagnosed with HFI.
- After intravenous administration of a sorbitol-containing medicine like eculizumab, patients with HFI may present with hypoglycemia, metabolic acidosis, seizures, coma, and it could be life threatening. Evaluate immediately if HFI is suspected and treat appropriately.
- For more information about BEKEMV (eculizumab), please refer to the patient leaflet or contact Medical Information by e-mail at: medinfo-mea@amgen.com
- 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@sfda.gov.sa Online: http://ade.sfda.gov.sa/

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Patients receiving eculizumab should always carry this card

Patient name_____

Hospital where treated_____

Doctor's name_____

Tel. number_____

Meningococcal vaccination date_____

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