BEKEMV®▼(eculizumab) PATIENT CARD

▼ This medicine 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 this 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.

Important Safety Information for Patients Receiving BEKEMV

Show this card to any doctor involved in your care.

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.

BEKEMV can lower the ability of your immune system to fight infections. Serious infections including sepsis may develop. 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 BEKEMV, keep this card with you for 3 months after your last BEKEMV dose. Your risk of meningococcal infection may continue for a long time after your last dose of BEKEMV.

This medicine contains sorbitol. 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. People with HFI cannot break down fructose, which may cause serious side effects, like seizures, coma, growth delay (in children), kidney and liver failure.

PATIENT CARD

Information for the Treating Doctor

This patient has been prescribed BEKEMV (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 recognised and treated early
- **Evaluate immediately if infection is suspected and treat with appropriate antibiotics if necessary**
- Contact prescribing doctor (below) as soon as possible.

- BEKEMV is contraindicated in patients with HFI regardless of their age, and in all 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 BEKEMV, patients with HFI may present with hypoglycaemia, metabolic acidosis, seizures and/or coma. These conditions can be life threatening. Evaluate immediately if HFI is suspected and treat appropriately.
- For more information about BEKEMV, please refer to the full Summary of Product Characteristics (https://www.medicines.ie/) or contact Amgen Medical Information on: +44 (0) 1223 436441, Freephone 1800 535 160 or email gbinfoline@amgen.com

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Patients receiving BEKEMV should carry this card at all times

Patient name _____

Hospital where treated _____

Doctor's name _____

Doctor's telephone number _____

Meningococcal vaccination date _____

Meningococcal re-vaccination date _____

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Ireland

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