Branch – Amgen (Europe) Gmbh
K.S.A–P.O Box 7561,Riyadh 12242
Centria Mall, 4th Floor
Olaya Street, Al Olaya
www.amgen.com

Vaccination Reminder

Important Safety Information

BEKEMV® ▼ (Eculizumab)

Additional Risk Minimisation Measures

On 6 Oct 2024 Amgen received the Marketing Authorisation for BEKEMV® 300 mg concentrate for solution for infusion, a biosimilar product of eculizumab intended for the treatment of Paroxysmal nocturnal haemoglobinuria (PNH) and Atypical haemolytic uremic syndrome (aHUS).

Amgen would like to inform you of the required additional Risk Minimisation Measures implemented in agreement with the Saudi Food & Drug Authority (SFDA) as part of the marketing authorisation for BEKEMV.

Additional Risk Minimisation Measures for BEKEMV consist of a Controlled Drug Distribution System and Educational Materials.

Controlled Drug Distribution System

For any orders received, BEKEMV distribution will only be made after receipt of written confirmation from a hospital that the patient has received or will receive meningococcal vaccination and/or antibiotic prophylaxis as described in the product label. Written confirmation must be provided in the form of a completed Vaccination/Prophylaxis Antibiotic Certificate. The Vaccination/Prophylaxis Antibiotic Certificate will be required from the hospital at the first order (placed at the distributor). All initial confirmations will be owned and archived by the distributor under the distributor quality systems & procedures.

Upon delivery of BEKEMV, it is the responsibility of the hospital to ensure the product is only given to the vaccinated patients.

Please find attached a copy of BEKEMV Vaccination/Prophylaxis Antibiotic Certificate.

Educational Materials

The **Educational Package** consisting of:

- Physician's Guide
- Patient's/Parent's Information Brochure
- Patient Safety Card.

These Educational Materials contain important information on safety concerns associated with BEKEMV treatment and how to mitigate these risks, including but not limited to:

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- Increased risk of severe infection and sepsis, including meningococcal infections
- Mandatory vaccination requirements
- Infusion reactions including anaphylaxis
- Sorbitol content warning and contraindication of BEKEMV in patients with hereditary fructose intolerance (HFI) regardless of their age, and in children less than 2 years of age, who may have not yet been diagnosed with HFI.

The prescribing physician should explain these key risks to patients/parents/legal guardians, ensure their understanding of how to mitigate these risks and provide them with copies of the Patient's/Parent's Information Brochure and Patient Safety Card before commencing the treatment with BEKEMV.

Call for reporting

▼ Reporting of any safety information will result in a quick identification of any new safety data. 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
Fax: +966-11-2057662
E-mail: npc.drug@sfda.gov.sa Online: http://ade.sfda.gov.sa/

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

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