

<Jul 13, 2026>

Direct Healthcare Professional Communication Letter

Vaccination reminder for Epysqli™▼ (eculizumab) 10 mg/ml solution for infusion, intravenous use, vial

Dear Healthcare Professional,

Samsung Bioepis in agreement with Saudi Food and Drug Authority would like to remind you about risk of severe infection and sepsis, and the need for re-vaccination for patients on Epysqli™.

Summary

Eculizumab products are required as part of their license to educational materials, vaccination reminders, which have been developed as additional Risk Minimisation Measures (aRMMs), considered necessary to supplement routine materials and enhance the overall risk-benefit balance.

Further information on the safety concern and the recommendations

This letter is a friendly reminder for the Healthcare professionals to check if a re-vaccination against *N.meningitidis* is needed for his/her patients on Epysqli™.

Treatment with eculizumab increases the risk of severe infection and sepsis, especially of *N. meningitidis*, which may lead to a fatal outcome. Therefore, it is important that patients on eculizumab are vaccinated against *N.meningitidis* or receive appropriate antibiotic therapy according to the current national vaccination guidelines for vaccination use.

Contact details for further information

If you have any further questions, or wish to receive more information or materials, please contact the medical information department of Samsung Bioepis at +XXX XXXX XXXXX.

To report any side effect(s), please contact:

The National Pharmacovigilance Centre (NPC) - Saudi Food and Drug Authority (SFDA):

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: <https://ade.sfda.gov.sa>



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Or

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Yours sincerely,