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IMPORTANT PRESCRIBING INFORMATION

SUBJECT: Change in Schedule for Administration of BEXSERO [Meningococcal Group B Vaccine]

Date: August 23, 2024

Dear Health Care Provider,

The purpose of this letter is to *inform you* of an important change to the *schedule for administration of BEXSERO*. The *Dosage and Administration* section of the US Prescribing Information (USPI) for *BEXSERO* has been revised. The approved dosing schedules presented in **Section 2.1 *Dose and Schedule*** are as follows:

- **Two-dose schedule:** Administer a dose (0.5 mL) at 0 and 6 months. If the second dose is administered earlier than 6 months after the first dose, a third dose should be administered at least 4 months after the second dose.
- **Three-dose schedule:** Administer a dose (0.5 mL) at 0, 1-2, and 6 months.

The choice of dosing schedule may depend on the risk of exposure and the individual's susceptibility to meningococcal serogroup B disease.

This is a change from the previous, no longer approved, schedule in which 2 doses (0.5 mL each) of BEXSERO were administered at least one month apart. The change in schedule is based on new data from a clinical trial ([NCT04502693](#)), referred to as Study 1 in the USPI.

BEXSERO is a vaccine indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B for use in individuals aged 10 through 25 years.

PRESCRIBING ACTION

Counsel vaccine recipients about the benefits and risks of *BEXSERO* and the importance of completing the vaccination series according to one of the approved dosing schedules.

REPORTING ADVERSE EVENTS

To report SUSPECTED ADVERSE REACTIONS, contact GSK at 1-888-825-5249 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

You may also contact GSK Medical Information at 1-877-475-6448 if you have any questions about the information contained in this letter or the safe and effective use of *BEXSERO*.

This letter is not intended as a complete description of the benefits and risks related to the use of *BEXSERO*. For more details, please refer to the enclosed full [Prescribing Information](#).

Sincerely,

Tosin Olaiya

Tosin Olaiya, MBChB, MSc

Medical Director, Medical Affairs – Neisseria Vaccines

Enclosure: *BEXSERO* Prescribing Information