

Air Bubble in *Bexsero* OnePFS Presentation

Summary

- Following the implementation of a new prefilled syringe (called “OnePFS”) presentation for *Bexsero* (Meningococcal Group B Vaccine), some complaints have been received related to the difficulty/impossibility to expel the air bubble before product administration.¹
- GSK vaccines or diluents delivered in prefilled syringes typically contain an air bubble (also known as “head space”) resulting from the manufacturing process.²
- GSK does not recommend expelling the air bubble in the prefilled syringe for vaccine administration via intramuscular injection method, unless differently recommended by local recommendations.¹ Given that the air volume in the prefilled syringe is at a typical volume of 0.2–0.3 cc, a product quality and safety impact assessment concluded that no impact on product quality has been identified.¹
- General recommendations from Immunize.org regarding expelling air bubbles from prefilled syringes can be found [here](#).
- Natural rubber latex may cause allergic reactions. GSK is transitioning vaccine products to a prefilled syringe that is not made with natural rubber latex. The tip cap of the prefilled syringe for *Bexsero* may or may not be made with natural rubber latex. Please check the carton and accompanying Prescribing Information.^{3,4}
- Important safety information can be found in the [Prescribing Information](#) for *Bexsero* and can also be accessed at [GSK Products](#).

To access additional scientific information related to GSK medicines, visit the GSK US Medical Affairs website at gskusmedicalaffairs.com.

GSK US
Medical Affairs
Website

Bexsero is a vaccine indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B.³ *Bexsero* is approved for use in individuals aged 10 through 25 years.

GENERAL RECOMMENDATIONS FROM IMMUNIZE.ORG

"Some single-dose manufacturer-filled vaccines come with an air pocket in the syringe chamber. Do we need to expel the air pocket before vaccinating? ... No. You do not need to expel the air pocket. The air will be absorbed."⁵

"It is not wrong to expel the air from syringes filled by manufacturers, but typically it is such a small amount of air (0.2–0.3 cc) that it is CDC's opinion that it would not cause a problem. When the syringe is inverted during an injection, that small amount of air would typically just clear the medication from the needle."⁵

Please refer to <https://www.immunize.org/> for the most current information from Immunize.org.

Trademarks are owned by or licensed to the GSK group of companies.

This information is scientific and non-promotional in nature and is not intended for further distribution. This information is not intended to offer recommendations for using this product in a manner inconsistent with its approved labeling. Please consult the Prescribing Information. For GSK to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 888-825-5249. Selection of references follows principles of evidence-based medicine and, therefore, references may not be all inclusive.

REFERENCES

1. Data on File. 2024N556530.
2. Data on File. 2014N224620.
3. Prescribing Information for *Bexsero*.
4. Prescribing Information for *Bexsero*, January 2022.
5. Immunize.org. Ask the Experts: Administering Vaccines. <https://www.immunize.org/ask-experts/topic/admin-vaccines/>. Reviewed December 28, 2022. Accessed September 19, 2024.