

SIMPONI® (subcutaneous golimumab)
STELARA® (ustekinumab)
TREMFYA® (guselkumab)
Air Bubble in Prefilled Syringe and Prefilled Syringe-based Injectors

SUMMARY

- Please refer to the full PRESCRIBING INFORMATION, MEDICATION GUIDE, and INSTRUCTIONS FOR USE regarding the proper administration technique and instructions for the following prefilled syringe and prefilled syringe-based injection device products:
 - SIMPONI prefilled syringe¹
 - SIMPONI SmartJect® autoinjector¹
 - STELARA prefilled syringe²
 - TREMFYA prefilled syringe³
 - TREMFYA prefilled pen (TREMFYA PEN)³
 - TREMFYA One-Press patient-controlled injector³
- The SIMPONI prefilled syringe, SIMPONI SmartJect autoinjector, STELARA prefilled syringe, TREMFYA prefilled syringe, TREMFYA prefilled pen (TREMFYA PEN), and TREMFYA One-Press patient-controlled injector are to be injected subcutaneously.¹⁻⁴
- It is normal to see an air bubble or bubbles in the prefilled syringe and prefilled syringe-based injection device products.⁴

AIR BUBBLE IN PREFILLED SYRINGE

- Due to the requirements of the fill/finish process and mechanical placement of the stopper in the syringe, there is a headspace (also known as void space) in the syringe.⁴
- The bubble/void space positioning can vary within the liquid depending on the prefilled syringe or prefilled syringe-based injection device orientation.⁴
- It is normal to see bubble or bubbles in the prefilled syringe or prefilled syringe-based injection device product.⁴

REFERENCES

1. SIMPONI ARIA (golimumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc; <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI+ARIA-pi.pdf>.
2. STELARA (ustekinumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc; <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf>.
3. TREMFYA (guselkumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc; <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf>.
4. Data on File. Technical Memorandum - Air bubble in SIMPONI (subcutaneous golimumab) prefilled syringe, SIMPONI SmartJect autoinjector, STELARA (ustekinumab) prefilled syringe, TREMFYA (guselkumab) prefilled syringe, TREMFYA prefilled pen, and TREMFYA One-Press patient-controlled injector; 2023.