



May 30, 2023

SIMPONI® (golimumab): Important Changes to the Instructions for Injecting SIMPONI® Using the SmartJect® Autoinjector

Dear Healthcare Professionals,

The purpose of this letter is to inform you of important changes to the instructions for injecting SIMPONI® using the SmartJect® Autoinjector.

What is the issue?

Following product complaints and adverse events related to the SmartJect® autoinjector for SIMPONI®, the following safety issues were identified:

- Bent or hooked needles that may require medical/surgical intervention to remove the needle from the injection site, most commonly occurring with arm injections;
- Accidental needle stick injuries to the healthcare provider or caregiver when pinching the skin during the injection;
- Inability to depress the autoinjector button and initiate the injection due to users pressing the button prematurely.

These issues concern the SIMPONI® SmartJect® autoinjector only.

Changes to the Product Monograph for SIMPONI®

The instructions for injecting SIMPONI® using the SmartJect® autoinjector have been updated. Key changes are:

- **The arm should not** be used as an injection site for the SmartJect® autoinjector.
- Only the front of the thigh or the lower abdomen should be used as injection sites for the SmartJect® autoinjector.
- **The skin should not be pinched**, when positioning the autoinjector flat against the skin or when administering the injection.

Other key information

- If administration in the arm is preferred, injections should only be given using the SIMPONI® prefilled syringe.
- In addition, it is important to note that failure of the device to actuate may result from prematurely pressing the button. To ensure proper actuation of the device,
 - the **open end of the autoinjector should be pushed straight against the skin** in order to slide the green safety sleeve inside the clear cover.
 - the **button should not be pressed** until after the green safety sleeve has completely slid into the clear cover.
 - follow the sequence of steps described in the Patient Medication Information section of the Product Monograph.
- SIMPONI® is intended for use under the guidance and supervision of a physician. Patients may self-inject with SIMPONI® after initial training in proper subcutaneous injection technique and if a physician determines that it is appropriate.

Information for Healthcare professionals

- Prescribers are expected to **share this communication with the personnel in their office/institution** who are involved in educating patients and/or their caregivers on the SIMPONI® SmartJect® autoinjector.
- **Inform all patients/caregivers**, including those who were previously trained, about the proper use of the autoinjector in accordance with the revised instructions.
- Please refer to the PATIENT MEDICATION INFORMATION for comprehensive instructions for injecting SIMPONI® using the SmartJect® autoinjector (<https://www.janssen.com/canada/our-medicines>, SIMPONI®/SIMPONI® IV, Patient Medication Information, p5-10). The current SIMPONI® Product Monograph with full prescribing information is also available at <https://www.janssen.com/canada/our-medicines>.

Report health or safety concerns

Managing marketed health product-related adverse reactions depends on healthcare professionals and consumers reporting them. Any adverse event, other serious or unexpected side effects, or medication incidents/errors associated with the use of SIMPONI® should be reported to Janssen Inc., or Health Canada at the addresses provided below.

Drug Safety & Risk Management Department

Janssen Inc.

19 Green Belt Dr.

Toronto, ON, M3C 1L9

Telephone: 1-866-825-7122 (toll free)

Fax: 1-866-767-5865

Email: dsscan@its.jnj.com

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax.

Should you have any questions or require additional information, please contact Janssen Inc. Medical Information at 1-800-567-3331.

Katherine Tsokas, Esq

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Janssen Inc.

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