Important medicines safety information

26 September 2023

Golimumab SIMPONI® 50 mg: Important Changes to the Instructions For Use (IFU) for the SmartJect® Autoinjector/Pre-filled Pen

Dear Healthcare Professional

Janssen Pharmaceutica, the holder of the certificate of registration for Simponi 50 mg in agreement with the South African Health Products Regulatory Authority (SAHPRA) would like to inform you of the steps taken to reduce the risks associated with administration of the product.

Background of the medicine and safety concern

SIMPONI® 50 mg golimumab in 0,5 mL solution for Injection for subcutaneous administration is indicated for:

- Rheumatoid arthritis;
- Polyarticular juvenile idiopathic arthritis;
- Psoriatic arthritis;
- Ankylosing spondylitis;
- Non-radiographic axial spondyloarthritis; and
- Ulcerative colitis.

During a recent global investigation of product complaints and adverse events related to the autoinjector, the following safety issues were identified by Janssen Pharmaceutica:

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

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Accordingly, Janssen Pharmaceutica has revised the SIMPONI SmartJect® instructions for use (IFU). This dear healthcare (DHPC) letter is intended to inform you about the revised IFU.

Details of the revised Instructions for Use:

- Do not put the cap of the pre-filled pen back if it has been removed to avoid bending the needle.
- The front of the thigh or the lower abdomen should be used as injection sites. The arm should not be used as an injection site for the Simponi SmartJect® autoinjector/ pre-filled pen.
- The pre-filled pen should be held comfortably with one hand, above the blue button, to avoid touching or pressing the button prematurely.
- The open end of the autoinjector should be pushed straight against the skin (at a 90-degree angle) in order to slide the green safety sleeve inside the clear cover. The blue button should not be pressed until after the green safety sleeve has completely slid into the clear cover. Only the wider portion of the green sleeve remains outside of the transparent cover.
- The skin should not be pinched when positioning the autoinjector/ pre-filled pen flat against the skin or when administering the injection.
- The hand not holding the pre-filled pen should be used to press the blue button to start the injection.
- The sequence of steps described in the IFU must be followed to ensure proper actuation of the device for injection.

Advice to Healthcare Professionals:

- Prescribers must share this communication with other healthcare professionals who are involved in educating patients and/or their caregivers on the SIMPONI SmartJect® autoinjector / pre-filled pen. All patients/caregivers should be informed on the proper use of the autoinjector/ pre-filled pen in accordance with the revised IFU. This would include those who were previously educated using the prior IFU.

- In addition, the Instructions for use in the Patient Information leaflet has been revised to provide clarity. Key changes include: eliminating the arm as an injection site for the autoinjector (only the thigh or abdomen should be used); eliminating pinching the skin, when positioning the autoinjector on the skin and when administering the injection.

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- Failure of the device to actuate can result from prematurely pressing the button. The sequence of steps described in the IFU must be followed in order to ensure proper actuation of the device for injection. The device must be pushed against the skin until the green safety sleeve slides completely into the clear cover BEFORE the button is pressed.

- All patients/caregivers, including those previously trained on the SIMPONI SmartJect® autoinjector/ pre-filled pen, should be informed on the proper use of the autoinjector in accordance with the revised IFU.

- Healthcare professionals are urged to report all suspected adverse events associated with the use of SIMPONI® to SAHPRA via Med Safety App that can be downloaded into a smart mobile phone through google Play or App store. For more information on Med Safety App, please visit SAHPRA website.

- Alternatively, reporting can be done via the eReporting link available on the SAHPRA website (www.sahpra.org.za). Additionally, the ADR reporting form accessible via the SAHPRA website at https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/ can be completed and emailed to adr@sahpra.org.za.

- For more information on ADR reporting, please contact the SAHPRA vigilance unit at pvqueries@sahpra.org.za or alternatively use the contact details below:

PRODUCT	ACTIVE	REGISTRATION NUMBER	CONTACT DETAILS Pharmacovigilance Unit	CONTACT DETAILS Medical Information
SIMPONI®50 mg pre-filled pen	golimumab	43/30.1/0808	**Tel:** +2711 518 7100 **Fax:** +2786 687 8942 or +2711 518 7108 Email: AdverseEventZA@its.jnj.com	**Tel:** 0860111117 **E-mail:** RA-medinfoemmarkets@its.jnj.com

Yours Faithfully,

Vanessa Snow

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Head of Medical Affairs

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