27th Dec 2023

Core Direct Healthcare Professional Communication (Core DHPC)

SIMPONI® (golimumab) 50 mg and 100 mg: Important Changes to the Instructions For Use (IFU) for the SmartJect® <Autoinjector/Prefilled Pen>

Dear Healthcare Professional,

Janssen-Cilag International NV in agreement with the European Medicines Agency and the Ministry of Health in Oman would like to inform you of the following:

Summary

- **Janssen has received several product complaints/adverse event reports involving the SmartJect® autoinjector for SIMPONI®. These included accidental needle stick injuries, bent or hooked needles, and failure of the device to actuate.**
- **The instructions for use (IFU) for the autoinjector have been revised. 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.**
- **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 SmartJect® autoinjector, should be informed on the proper use of the autoinjector in accordance with the revised IFU.**

Background of the safety concern

SIMPONI® is available as a solution for monthly subcutaneous administration. In some markets, more than one delivery device presentation is available (SmartJect® autoinjector and Simponi® prefilled syringe). This safety communication concerns the SmartJect® autoinjector only.

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

- 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;
- Inability to depress the autoinjector button and initiate the injection due to users pressing the button prematurely.

Accordingly, Janssen has revised the SmartJect® IFU. This DHPC is intended to inform you about the revised IFU.

Highlights of the revised IFU:

- 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 SmartJect® autoinjector.** <Injections in the arm should only be given using the Simponi® prefilled syringe>.
- 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 button should not be pressed until after the green safety sleeve has completely slid into the clear cover.
- **The skin should not be pinched** when positioning the autoinjector flat against the skin or when administering the injection.

Requested action:

- 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 SmartJect® autoinjector. All patients/caregivers should be informed on the proper use of the autoinjector in accordance with the revised IFU. This would include those who were previously educated using the prior IFU.

Call for reporting

Healthcare professionals should report any suspected adverse reactions associated with the use of Simponi in accordance with the national spontaneous reporting system: Department of Pharmacovigilance & Drug Information MOH

1. Tel: 0096822357686 & 0096822357687
2. Fax: +96822358489
3. www.moh.gov.om

Company contact points

For full prescribing information, please refer to the data sheet or contact Johnson & Johnson Middle East FZ LLC, Mohamed Bin Rashid Academic Medical Centre –Building 14, Level 4 – Dubai Healthcare City – Dubai 505080, United Arab Emirates Tel: +97144297200 Fax: +97144297150

To report Adverse Events/Product Complaint, please contact us at:

Email: GCC-PV2@its.jnj.com

24/7 PV Hotline: +971559816775

Yours Faithfully,

Mohab Hassan

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