PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Date: 09-Aug-2023

Simponi (golimumab) 50 mg and 100 mg: Important changes to the injection instructions for the SmartJect Pre-filled Pen.

Dear Healthcare Professional,

The marketing authorization holder of Simponi, Janssen Biologics B.V., and the local representative, Merck Sharp & Dohme Ireland (Human Health) Limited, in agreement with the European Medicines Agency and the Health Products Regulatory Authority, would like to inform you of the following:

Summary

- **Accidental needle stick injuries, bent or hooked needles, and device actuation failure have been reported for the Simponi SmartJect pre-filled pen.**
- **Instructions for use have therefore been revised as follows:**
  - **Do not put the cap of the pre-filled pen back if removed, to avoid bending the needle.**
  - **Only inject in the thigh or abdomen.**
  - **Use a two-hand approach to administer the injection (one hand to hold the pre-filled pen and the other hand to press the blue button to start the injection).**
  - **Do not pinch the skin, when positioning the pre-filled pen and when administering the injection.**
- **The device must be pushed against the skin until the green safety sleeve slides completely into the transparent cover BEFORE the blue button is pressed. Only the wider portion of the green safety sleeve remains outside of the transparent cover.**
- **All patients/caregivers, including those previously trained on the SmartJect pre-filled pen, should be instructed on the proper use of the device in accordance with the revised instructions for use.**

Background of the safety concern

SIMPONI is available as a solution for monthly subcutaneous administration. In the EU, more than one delivery device presentation is available (SmartJect pre-filled pen and Simponi pre-filled syringe). This safety communication concerns the SmartJect pre-filled pen only.

As per the approved product information, after proper training in subcutaneous injection technique, patients may self-inject if their physician determines this is appropriate, with retraining as necessary. Patients should be instructed to inject the prescribed amount of Simponi according to the comprehensive instructions for use (IFU) provided in the package leaflet.

An investigation of product complaints and adverse events related to the SmartJect pre-filled pen identified the following problems:

- 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 pre-filled pen button and initiate the injection due to users pressing the button prematurely.

Accordingly, the SmartJect IFU, which is located within the package leaflet in the product package, has been revised. This safety communication is intended to inform you about the revised IFU.

Highlights of the revised IFU:

- Do not put the cap of the pre-filled pen back if 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 SmartJect 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 pre-filled pen should be pushed straight against the skin at a 90-degree angle 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 transparent cover. Only the wider portion of the green safety sleeve remains outside of the transparent cover.
- **The skin should not be pinched** when positioning the 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.

Requested action:

- All patients/caregivers should be informed on the proper use of the pre-filled pen in accordance with the revised IFU. This would include those who were previously educated in using the prior IFU.
- This communication should be shared with personnel involved in educating patients and/or their caregivers on the SmartJect pre-filled pen.

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. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

Adverse reaction reports should also be reported to Merck Sharp & Dohme Ireland (Human Health) Limited. Please report the product name and batch details.

Company contact points

Marketing Authorisation Holder	**Local Representative**	**Email Contact**	**Phone Number**
Janssen Biologics B.V. Einsteinweg 101 2333 CB Leiden The Netherlands	Merck Sharp & Dohme Ireland (Human Health) Limited	medinfo_ireland@merck.com	+353 (0)1 2998700

The updated SmartJect IFU, which is located within the package leaflet in the product package, is available on www.medicines.ie.

Yours Sincerely,

André Oliveira

Associate Director, Medical Affairs

MSD Ireland (Human Health) Limited