Direct healthcare professional communication (DHPC)

Date: 9th August 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 authorisation holder of Simponi, Janssen Biologics B.V. / Janssen-Cilag Ltd., and the local representative, Merck Sharp & Dohme (UK) Limited/ Merck Sharp & Dohme Ireland (Human Health) Limited, in agreement with the European Medicines Agency and Medicines and Healthcare Products Regulatory Agency (MHRA), 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 in some cases, these events have prevented **patients from receiving the scheduled dose** of the medicine or caused patient injury;
- 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 indicated for some patients with rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, and ulcerative colitis – see the Summary of Product Characteristics for more information.

Simponi (golimumab) is available as a solution for monthly subcutaneous administration. In the UK, 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.

<u>Highlights of the revised IFU:</u>

- 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.

<u>Requested action:</u>

- 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.

The revised IFU is published and accessible on the Electronic Medicines Compendium for Great Britain and Northern Ireland:
IFU for 50mg and 100mg (GB): https://www.medicines.org.uk/emc
IFU for 50mg and 100mg (NI): https://www.emcmedicines.com/en-gb/northernireland

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.
Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website http://mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.
When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number. Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Adverse reactions should also be reported to the relevant company [see Table 1 for company contact details]. Please report the product name and batch details.

Company contact points

If you have any questions, or if you require any further information, please contact the relevant Medical Information Department [See Table 1 for company contact details].

Yours Sincerely,

Rina Kundi

Rina Kundi
Director of Medical Affairs

Merck Sharp & Dohme (UK) Limited

Table 1

Product name (active ingredient)	**Marketing Authorisation Holder**	**Local Representative**
SIMPONI® (golimumab)	Northern Ireland Janssen Biologics B.V.	United Kingdom (Northern Ireland) Merck Sharp & Dohme Ireland (Human Health) Limited Tel: +353 (0)1 2998700 e-mail: medinfoNI@msd.com
	Great Britain Janssen-Cilag Ltd (GB)	Great Britain Merck Sharp & Dohme (UK) Limited Tel: +44 (0) 208 154 8000 e-mail: medicalinformationuk@msd.com