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Gauteng, 2090

IMPORTANT MEDICINE SAFETY INFORMATION

SYBRAVA® (INCLISIRAN)

(Reg. No.: 55/7.5/0682)

IMPORTANT PRESCRIBING INFORMATION

Notice to Healthcare Professionals Regarding Instructions for Use for SYBRAVA (inclisiran) injection, 284 mg/1.5 mL (189 mg/mL) in a single-dose pre-filled syringe

01 December 2023

Dear Health Care Provider / Professional,

The purpose of this letter is to inform you that in collaboration with the South African Health Products Regulatory Authority (SAHPRA), Novartis South Africa (Pty) Ltd. is providing important new user handling instructions for the **Sybrava** (inclisiran) single-dose pre-filled syringe injection. **Sybrava** is indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C).

Recent Complaints with the Sybrava (inclisiran) Single-Dose Pre-filled Syringe Injection:

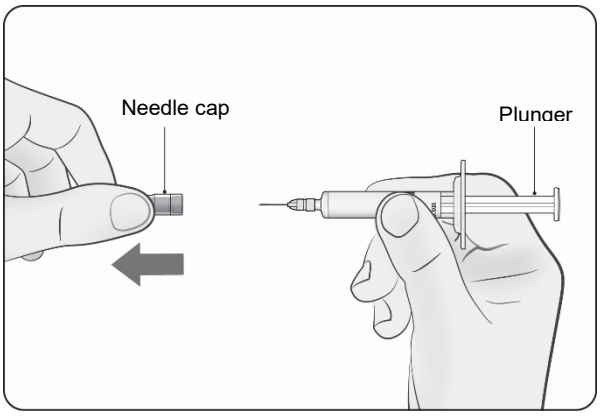
Novartis has received a small number of complaints associated with difficulty moving the syringe plunger that can result in the inability to inject **Sybrava**. This issue occurs infrequently globally (< 0.1%). The reviewed data confirms that there is no clinically relevant risk to patient safety.

To ensure optimal use of Sybrava for patients and healthcare professionals while technical solutions are investigated to alleviate the issue, Novartis is sharing with you important information for you to be aware of before injecting Sybrava (please see *Prescriber Actions* below).

Prescriber Actions:

Do not remove the needle cap until you are ready to inject (see *Figure 1* below). In rare cases, early removal of the needle cap prior to injection can lead to drying of the drug product within the needle, which can result in needle clogging.

Figure 1: Removal of needle cap on a pre-filled syringe:



If following insertion of the needle you cannot depress the plunger, use a new pre-filled syringe. Kindly report this to Novartis Quality Complaints email: qa.phzais@novartis.com. In order to receive a replacement for any impacted Sybrava syringes please contact your wholesaler or supplier.

Reporting Adverse Events:

Adverse drug reactions associated with the use of Sybrava should be reported to Novartis on the following email patientsafety.sacg@novartis.com or via the website https://www.novartis.com/report.

Alternatively, please complete the ADR reporting form accessible via the SAHPRA website at www.sahpra.org.za and email it to adr@sahpra.org.za.

You may also contact our Novartis on +27860 929 929 if you have any questions about the information contained in this letter or the safe and effective use of Sybrava.

Sincerely,

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Digitally signed by Padayachee Kumeshnie
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