NOVARTIS | Reimagining Medicine

Novartis South Africa (Pty) Ltd
PO Box 12257, Vorna Valley, 1686
The Novartis Building, Magwa Crescent West
Waterfall City, Jukskei View
Gauteng, 2090

https://www.novartis.com/za-en/

IMPORTANT MEDICINE SAFETY INFORMATION

INSTRUCTIONS FOR USE FOR SYBRAVA® (INCLISIRAN) SINGLE-DOSE PRE-FILLED SYRINGE

28 May 2024

Dear Healthcare Provider / Professional,

Novartis South Africa (Pty) Ltd, the holder of certificate of registration for Sybrava® (inclisiran) single-dose pre-filled syringe, in collaboration with the South African Health Products Regulatory Authority (SAHPRA), wishes to inform you about important new user handling instructions for the Sybrava® (inclisiran) single-dose pre-filled syringe injection, to reduce the risks associated with administration of the product.

Background on the safety concern

- Sybrava® single-dose pre-filled syringe is a subcutaneous injection, 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).

- Novartis has received complaints (< 0.1% globally) associated with difficulty in moving the syringe plunger that can result in the inability to inject Sybrava® single-dose pre-filled syringe.

- The reviewed data confirms that there is no clinically relevant risk to patient safety.

The Professional Information (PI) and Patient Information Leaflet (PIL) of Sybrava® (inclisiran) single-dose pre-filled syringe, will be updated to include the new user handling instructions for use of the product. Furthermore, Novartis is investigating technical solutions to alleviate this safety concern.

Advice to healthcare professionals

- To ensure optimal use of Sybrava® (inclisiran) single-dose pre-filled syringe, healthcare professionals are advised, not to remove the needle cap until they are ready to inject *(see Figure 1 below)*. Early removal of the needle cap prior to injection can lead to drying of the product within the needle, which can result in needle clogging.

- Healthcare professionals are advised to use a new pre-filled syringe, in case, the plunger does not depress following insertion of the needle.

- Healthcare professionals are urged to report any adverse drug reactions (ADRs) or product quality problems associated with the use of Sybrava® (inclisiran) single-dose pre-filled syringe to SAHPRA via the following eReporting link https://primaryreporting.who-umc.org/ZA available on the SAHPRA website (www.sahpra.org.za).

- Alternatively, ADRs associated with Sybrava® (inclisiran) single-dose pre-filled syringe can be reported to Novartis on the following email: patientsafety.sacg@novartis.com or via the website.

- Furthermore, healthcare professionals may complete the ADR reporting form accessible on SAHPRA website via this link: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/, and email it to adr@sahpra.org.za

- Reporting can also be done via the Med Safety App. The App can be downloaded into a smart phone through Google Play or App Store. For more information on the Med Safety App, please use the following link: https://medsafety.sahpra.org.za/.

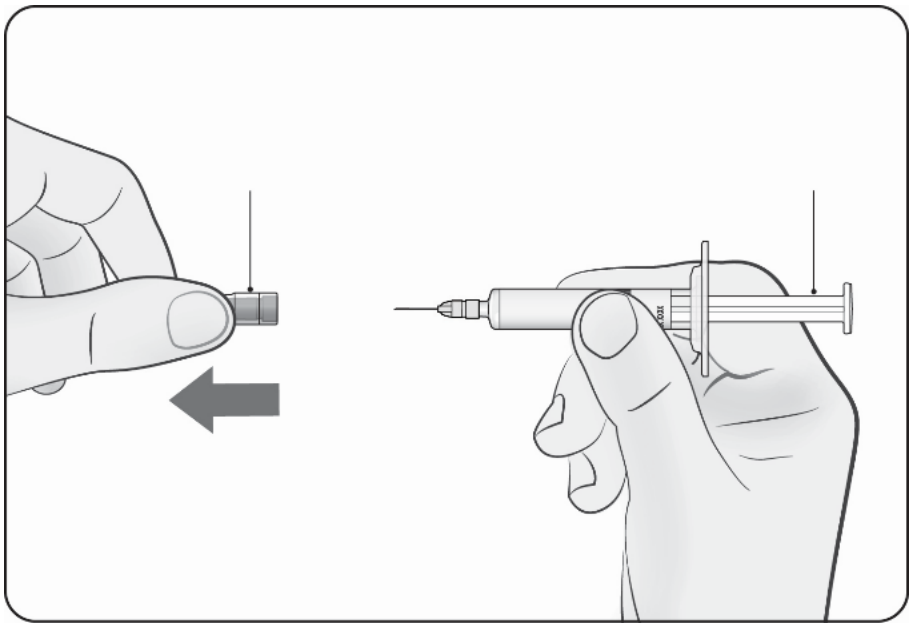
- Quality complaints associated with the use of Sybrava® (inclisiran) single-dose pre-filled syringe can be forwarded to Novartis via email: qa.phzais@novartis.com.

- Healthcare professionals are advised to contact the wholesaler or supplier for replacement of any impacted Sybrava® (inclisiran) single-dose pre-filled syringe.

- For more information on ADR reporting of Sybrava® (inclisiran) single-dose pre-filled syringe, please contact the SAHPRA Pharmacovigilance unit via email at pvqueries@sahpra.org.za.

- Healthcare professionals may also contact Novartis on +27860 929 929 for any questions about the information contained in this letter or the safe and effective use of Sybrava® (inclisiran) single-dose pre-filled syringe.

Figure 1: Removal of needle cap on a 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.

Sincerely,

Padayachee Kumeshnie

Digitally signed by Padayachee Kumeshnie
DN: dc=com, dc=novartis, ou=people, ou=GD, serialNumber=1426076, cn=Padayachee Kumeshnie
Reason: I am approving this document
Date: 2024.05.28 09:24:26 +02'00'

Kumeshnie Padayachee

Head of Regulatory Affairs and Responsible Pharmacist

Tel: +27 10 346 3900

Cell: +27 71 257 7096